

# EXHIBIT 4

In The Matter Of:  
***In Re: CR Bard 200***

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***Daniel Elliott M.D., Vol. II***

November 16, 2014

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IN THE UNITED STATES DISTRICT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: C.R. BARD, INC.,  
PELVIC REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL  
CASES IN MDL NO. 2187 AND  
SPECIFICALLY TO:

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ROSAIDA ALONSO,  
Plaintiff, Civil Action File  
No. 2:14-cv-07112

vs.  
C.R. BARD, INC.,  
Defendant.

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PATRICIA BOLYARD, et al.,  
Plaintiffs, Civil Action File  
No. 2:12-cv-00126

vs.  
C.R. BARD, INC.,  
Defendant,

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MARTINA WHEELER,  
Plaintiff, Civil Action File  
No. 2:12-cv-04580

vs.  
C.R. BARD, INC.,  
Defendant.

VOLUME II

The videotaped deposition of DANIEL S. ELLIOTT, M.D.,  
November 16, 2014

Wexler Wallace, 55 West Monroe Street, Suite  
3300, Chicago, Illinois, commencing at 8:54 a.m.  
Reporter: Jennifer L. Bernier

<p style="text-align: right;">Page 473</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 AYLSTOCK, WITKIN, KREIS &amp; OVERHOLTZ, PLLC</p> <p>4 MS. P. ANN GAYLE</p> <p>5 MR. BRANDON S. MORRIS</p> <p>6 17 East Main Street</p> <p>7 Suite 200</p> <p>8 Pensacola, Florida 32502</p> <p>9 Phone: (850) 202-1010</p> <p>10 E-mail: agayle@awkolaw.com</p> <p>11 bmmorris@awkolaw.com</p> <p>12</p> <p>13 On behalf of the Plaintiffs;</p> <p>14</p> <p>15 REED SMITH</p> <p>16 MS. MELISSA GEIST</p> <p>17 136 Main Street</p> <p>18 Suite 250</p> <p>19 Princeton Forrestal Village</p> <p>20 Princeton, New Jersey 08540</p> <p>21 Phone: (609) 514-5978</p> <p>22 E-mail: Mgeist@reedsmith.com</p> <p>23 On behalf of the Defendant.</p> <p>24</p> <p>25 ALSO PRESENT:</p> <p>John Doody, Videographer</p> <p style="text-align: center;">* * * * *</p>	<p style="text-align: right;">Page 475</p> <p>1 VIDEO TECHNICIAN: We're now on the record. The</p> <p>2 time is approximately 8:51 a.m.</p> <p>3 This is the beginning of Disc 1, Volume 2, of</p> <p>4 the video deposition of Dr. Daniel S. Elliot.</p> <p>5 Will counsel please identify yourselves for</p> <p>6 the record and state who you represent.</p> <p>7 MS. GAYLE: Patty Ann Gayle appearing for the</p> <p>8 plaintiffs, Wheeler, Alonso, and Bolyard, out of</p> <p>9 the firm of Aylstock Witkin in Pensacola,</p> <p>10 Florida.</p> <p>11 MR. MORRIS: Brandon Morris for the Plaintiffs from</p> <p>12 Aylstock, Witkin, Kreis &amp; Overholtz.</p> <p>13 MS. GEIST: Melissa Geist from Reed Smith for the</p> <p>14 defendant C.R. Bard.</p> <p>15 VIDEO TECHNICIAN: Would the court reporter remind</p> <p>16 the witness he's still under oath?</p> <p>17 THE REPORTER: Sir, you understand you're still</p> <p>18 under oath?</p> <p>19 <b>THE WITNESS: I do.</b></p> <p>20 (Witness previously sworn.)</p> <p>21 WHEREUPON:</p> <p>22 DANIEL S. ELLIOTT, M.D.,</p> <p>23 called as a witness herein, having been previously duly</p> <p>24 sworn, was examined and testified further as follows:</p> <p>25 DIRECT EXAMINATION (continued)</p>
<p style="text-align: right;">Page 474</p> <p>1 I N D E X</p> <p>2 WITNESS PAGE</p> <p>3 DANIEL S. ELLIOTT, M.D.</p> <p>4 Examination by Ms. Geist 476</p> <p>5 Examination By Ms. Gayle 747</p> <p>6 E X H I B I T S</p> <p>7 ELLIOTT DEPOSITION EXHIBITS PAGE</p> <p>8 No. #29 Alonso Report 477</p> <p>9 No. #30 AP IFU 509</p> <p>10 No. #31 Suarez Op Report 559</p> <p>11 No. #33 Wheeler Report 608</p> <p>12 No. #34 Wheeler Report 641</p> <p>13 No. #35 Bolyard Report 656</p> <p>14 No. #36 Marlex MSDS 717</p> <p>15 No. #37 '93 Marlex MSDS 717</p> <p>16 No. #38 '97 Marlex MSDS 717</p> <p>17 No. #39 Melkerson Letter 729</p>	<p style="text-align: right;">Page 476</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Good morning, Dr. Elliot.</p> <p>3 <b>A. Good morning.</b></p> <p>4 Q. We spent a considerable part of yesterday</p> <p>5 together, and I don't need to remind you of the rules of</p> <p>6 the deposition, I assume. You understand it's a</p> <p>7 question-and-answer period. We need to be careful not</p> <p>8 to talk over one another. And if I ask you anything you</p> <p>9 don't understand, will you let me know?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. So I can rephrase the question. And I think</p> <p>12 we worked pretty well yesterday under those rules?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Do you agree? Okay.</p> <p>15 <b>A. Yes.</b></p> <p>16 MS. GAYLE: And, Counsel, before you get started,</p> <p>17 just for the record, it's our position that you're going</p> <p>18 to take no more than two hours per case today on each of</p> <p>19 these individual cases.</p> <p>20 MS. GEIST: Well, and let me just add that we don't</p> <p>21 have any formal agreement. I'm not going to limit</p> <p>22 myself to time. I'm going to do my best to be as</p> <p>23 efficient as possible. I know we all want to catch</p> <p>24 flights. So let me -- let me start by asking the doctor</p> <p>25 if a couple of things are agreeable, and then we'll see</p>

<p style="text-align: right;">Page 477</p> <p>1 if we can be efficient.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. Dr. Elliott, yesterday you provided testimony</p> <p>4 with respect to your generic opinions that you're</p> <p>5 offering in this litigation, correct?</p> <p>6 <b>A. Correct.</b></p> <p>7 Q. And you understand, today, that we're focusing</p> <p>8 on the specific opinions you've provided in three</p> <p>9 reports for three separate plaintiffs, correct?</p> <p>10 <b>A. Yes.</b></p> <p>11 Q. Would you agree with me, Doctor, that some of</p> <p>12 the opinions in your report for the three separate</p> <p>13 plaintiffs are identical in certain respects?</p> <p>14 <b>A. In certain respects they're going to be, yeah,</b></p> <p>15 <b>very similar, if not identical.</b></p> <p>16 (Elliott Deposition Exhibit No. 29</p> <p>17 was marked for identification.)</p> <p>18 BY MS. GEIST:</p> <p>19 Q. Okay. So, for example, if you look at what</p> <p>20 I've already marked as Exhibit 29 to your deposition,</p> <p>21 that's a case-specific expert report for Rosaida Alonso?</p> <p>22 <b>A. Correct.</b></p> <p>23 Q. If you look at page 8 of that report, in the</p> <p>24 first full paragraph, it says, Set out in my general</p> <p>25 causation expert report several characteristics of the</p>	<p style="text-align: right;">Page 479</p> <p>1 <b>A. Yes, I do.</b></p> <p>2 Q. Similarly, by my review, that section of the</p> <p>3 report, pages 8 through 11, when you talk about the</p> <p>4 risks that should have been placed in the IFU, that is</p> <p>5 identical to the information and opinions you've</p> <p>6 provided in the reports for Mrs. Wheeler and</p> <p>7 Mrs. Bolyard, correct?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. So, again, if I can explore the basis for your</p> <p>10 opinions here in Mrs. Alonso's case, we don't need to go</p> <p>11 through the same information and I don't need to ask you</p> <p>12 the same questions in the other two cases, do you agree?</p> <p>13 MS. GAYLE: It's our -- before I let him answer</p> <p>14 that, Counsel, it's our position that these generic</p> <p>15 types of opinions that are in these three are -- as</p> <p>16 you've said, they are similar, but they also go back to</p> <p>17 his general opinions from yesterday. And so it's our</p> <p>18 position that they really don't need to be rehashed at</p> <p>19 all because they're part of his general opinions.</p> <p>20 They're just incorporated into these case reports.</p> <p>21 MS. GEIST: Well, the only thing I'll say about</p> <p>22 that is, I am entitled to explore them. They're not set</p> <p>23 forth as just general opinions. In the report itself,</p> <p>24 it specifically talks about how they apply to each</p> <p>25 individual case.</p>
<p style="text-align: right;">Page 478</p> <p>1 Marlex polypropylene mesh render it inherently unsafe</p> <p>2 for use in Ms. Alonso. And then you describe five</p> <p>3 different reasons why the Marlex polypropylene mesh is</p> <p>4 inherently unsafe for use in Ms. Alonso.</p> <p>5 And this paragraph is identical in the reports</p> <p>6 you have also rendered for the two other plaintiffs</p> <p>7 we're going to speak about today, correct?</p> <p>8 <b>A. Correct.</b></p> <p>9 Q. Okay. So what I'm trying to do is see if we</p> <p>10 have an agreement that I don't need to reask or go</p> <p>11 through these same issues with you in the cases for</p> <p>12 Mrs. Wheeler and Mrs. -- I want to make sure I got her</p> <p>13 name right -- Bolyard, B-O-L-Y-A-R-D. So anything I ask</p> <p>14 you here, when we talk about Ms. Alonso, can we apply</p> <p>15 your answers to the other two cases?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. And so then we don't have to repeat and try to</p> <p>18 be efficient and quick as possible?</p> <p>19 <b>A. Absolutely.</b></p> <p>20 Q. Okay. Similarly, you have some opinions, in</p> <p>21 each of your three case-specific expert reports, that</p> <p>22 deal with the risks that you will opine Bard knew about</p> <p>23 and, therefore, should have put in the IFU. And that</p> <p>24 section of your Alonso report is pages 8 through 11. Do</p> <p>25 you see that, Doctor?</p>	<p style="text-align: right;">Page 480</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Is that correct, Doctor?</p> <p>3 <b>A. Correct.</b></p> <p>4 Q. So, anyway, the point is, I don't want to have</p> <p>5 to reask you the same types of questions in the other</p> <p>6 two cases. So do you agree whatever I ask you relating</p> <p>7 to the information in the IFU, et cetera, can apply to</p> <p>8 the other two cases; is that fair?</p> <p>9 <b>A. I agree with that unless I think of something</b></p> <p>10 <b>that does not quite correlate; but I agree with you,</b></p> <p>11 <b>yeah.</b></p> <p>12 Q. That's fine. Thank you. Doctor, yesterday,</p> <p>13 when we began your deposition relating to your generic</p> <p>14 opinions, I asked you if you could tell me how much time</p> <p>15 you spent on the cases. Do you remember that?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. And you were unable to give me any information</p> <p>18 or any documents really into how much time you spent on</p> <p>19 the cases, correct?</p> <p>20 <b>A. Correct.</b></p> <p>21 Q. I assume you didn't go back and look into that</p> <p>22 so you could tell me more information today?</p> <p>23 MS. GAYLE: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 <b>A. That is correct.</b></p>

<p style="text-align: right;">Page 481</p> <p>1 Q. And you don't have any invoices or paperwork 2 or correspondence with you that would help us understand 3 how much time you spent in formulating your generic and 4 case-specific opinions?</p> <p>5 <b>A. I do not have those with me, no.</b></p> <p>6 Q. Did I also understand you correctly from 7 yesterday that you've never broke out separately how 8 much time you've spent on Mrs. Alonso's case 9 specifically separate from your generic opinions; is 10 that right?</p> <p>11 <b>A. No. There is an itemized invoice sent to 12 Mr. Anderson's office of each individual and how much 13 time was spent reviewing medical records, IME exams, 14 those types of things.</b></p> <p>15 Q. So -- and Mr. Anderson is an attorney 16 representing the plaintiffs in this litigation?</p> <p>17 <b>A. I don't know how to answer that. He was 18 the -- he is the one that I've been told to send my 19 invoice to, to his office, his paralegal.</b></p> <p>20 Q. So just so I understand, when you invoice, do 21 you provide a separate invoice for your generic work and 22 then a separate invoice for each individual plaintiff's 23 case that you work on and provide opinions for?</p> <p>24 <b>A. There will be a section broken down into 25 generic work, review of documentation, internal</b></p>	<p style="text-align: right;">Page 483</p> <p>1 <b>submitted.</b></p> <p>2 Q. Okay. You don't have an estimate or an 3 approximation for me how much time you spent in forming 4 your opinions on Mrs. Alonso's case as you sit here 5 today?</p> <p>6 <b>A. No, I do not.</b></p> <p>7 MS. GEIST: Okay. And, Counsel, I would just make 8 a formal request for the invoices that Dr. Elliott has 9 submitted to Mr. Anderson's office for all of his work 10 done in formulating his generic opinions as well as his 11 opinions in the three specific plaintiffs' cases we're 12 discussing here today. Thank you.</p> <p>13 BY MS. GEIST:</p> <p>14 Q. How did you go about preparing and formulating 15 your opinions specific to Mrs. Alonso?</p> <p>16 <b>A. Initially, medical records were sent to me 17 electronic -- I don't have any paper records -- of all 18 of the medical records pertaining to her care prior and 19 after her initial surgery. So I reviewed those and then 20 also reviewing the pertinent literature that would come 21 about through my research on her case.</b></p> <p>22 Q. And if we refer to your expert report that 23 we've marked as Exhibit 29, that's the report that you 24 provided for Mrs. Alonso; is that correct, Doctor?</p> <p>25 <b>A. Correct.</b></p>
<p style="text-align: right;">Page 482</p> <p>1 <b>documents, medical records -- not records, excuse me -- 2 manuscripts. That will be in the general. And then it 3 will be broken down into the various different 4 individuals, how much time was spent reviewing their 5 medical records, how much time was spent during the IME.</b></p> <p>6 Q. So it's -- it's all in the same invoice, but 7 there is a separate section for Mrs. Alonso. Is that 8 what I am hearing from you, Doctor?</p> <p>9 <b>A. That would be -- that would be correct.</b></p> <p>10 Q. Okay.</p> <p>11 <b>A. But just because Alonso, or whomever, has a 12 certain amount of allotted time, that does not 13 necessarily correlate to that was the only time spent on 14 the individual because the general review of literature, 15 everything, will actually correlate to them, these 16 individuals, too.</b></p> <p>17 Q. Your general review of literature helped you 18 inform your opinions about each specific case; is that 19 what you're telling me?</p> <p>20 <b>A. That is correct.</b></p> <p>21 Q. Okay. So for Mrs. Alonso, specifically, can 22 you tell me how much time you spent on her case?</p> <p>23 <b>A. No, I can't, because I don't have those 24 records. That would be retrievable through 25 Mr. Anderson's office and the invoices that were</b></p>	<p style="text-align: right;">Page 484</p> <p>1 Q. And that has a number of attachments to it 2 starting with Exhibit A. And that's your CV, correct?</p> <p>3 <b>A. Correct.</b></p> <p>4 Q. And the only updates that need to be made to 5 that CV are a couple of things you noted to me yesterday 6 when we discussed your generic opinions, correct?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. And then Exhibit B also provides your fee 9 schedule and testimony history, and that's the same as 10 you provided to us in your generic report, correct?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. And then Exhibit C has a list of materials 13 reviewed and relied upon, and you incorporate your 14 general report here as well, correct?</p> <p>15 <b>A. Correct.</b></p> <p>16 Q. And with respect to that general report, you 17 provided us, a day or two before your deposition 18 yesterday, with an updated literature review list or 19 bibliography, correct?</p> <p>20 <b>A. Well, I don't know when it arrived to you. I 21 sent it to the lawyers on Monday or Tuesday, something 22 like that.</b></p> <p>23 Q. Okay. But I assume you wish to incorporate 24 your updated bibliography here in Mrs. Alonso's case?</p> <p>25 <b>A. Correct.</b></p>

<p style="text-align: right;">Page 485</p> <p>1 Q. And then, if you look at the second and third</p> <p>2 page of what is Exhibit C to your report in</p> <p>3 Mrs. Alonso's case, that appears to list what I will</p> <p>4 call the case-specific records for Mrs. Alonso?</p> <p>5 <b>A. Yeah. These are the medical records that I</b></p> <p>6 <b>reviewed pertaining to her care.</b></p> <p>7 Q. You also have listed here depositions as well,</p> <p>8 correct?</p> <p>9 <b>A. Correct. Yeah. And I assume -- and there's</b></p> <p>10 <b>four -- four depositions. So it's medical records and</b></p> <p>11 <b>depositions.</b></p> <p>12 Q. And who is Mr. Gill?</p> <p>13 <b>A. Oh, Mr. Gill. I would have to go back and</b></p> <p>14 <b>look at the records of who Mr. Gill is. I can't recall.</b></p> <p>15 Q. And how about Dr. Juan Suarez? Who is that?</p> <p>16 <b>A. Suarez was the implanting surgeon.</b></p> <p>17 Q. And how about Dr. Carlos Medina?</p> <p>18 <b>A. Carlos Medina is the surgeon who took care of</b></p> <p>19 <b>the complications, some of the complications, I should</b></p> <p>20 <b>say.</b></p> <p>21 Q. And on Exhibit C, on pages 2 and 3, is this a</p> <p>22 complete list of all of the case-specific records you</p> <p>23 reviewed in reaching your opinions with respect to</p> <p>24 Mrs. Alonso?</p> <p>25 <b>A. Correct.</b></p>	<p style="text-align: right;">Page 487</p> <p>1 are listed there on page 3 of Exhibit C? Did you review</p> <p>2 those depositions in their entirety or were you provided</p> <p>3 with excerpts only?</p> <p>4 <b>A. Their entirety, all four. And that would</b></p> <p>5 <b>pertain to everybody else, Bolyard and Wheeler as well.</b></p> <p>6 Q. Okay. Perfect. So I can just go ahead and</p> <p>7 use your answers for those --</p> <p>8 <b>A. Extrapolate.</b></p> <p>9 Q. -- cases as well? Thank you for that. Are</p> <p>10 all of your opinions with respect to Mrs. Alonso's case</p> <p>11 set forth here, Doctor, in your expert report?</p> <p>12 <b>A. Yes, they are, unless new material were</b></p> <p>13 <b>provided to me. But, yes.</b></p> <p>14 Q. As of now, this is what I would refer to as</p> <p>15 your complete analysis of the case?</p> <p>16 <b>A. That is correct.</b></p> <p>17 Q. You mentioned already a couple of times an</p> <p>18 IME. So let me ask you about that. Did you perform an</p> <p>19 independent medical exam for Mrs. Alonso?</p> <p>20 <b>A. Yes, I did.</b></p> <p>21 Q. And did you also do that for Mrs. Wheeler</p> <p>22 and --</p> <p>23 <b>A. Bolyard.</b></p> <p>24 Q. -- Mrs. Bolyard?</p> <p>25 <b>A. Yes, I did.</b></p>
<p style="text-align: right;">Page 486</p> <p>1 Q. Were all of these records sent to you</p> <p>2 initially when you were asked to do an expert report in</p> <p>3 this case?</p> <p>4 <b>A. I can't recall that. I received large batches</b></p> <p>5 <b>of medical records. There may be a possibility that I</b></p> <p>6 <b>went through and reviewed and found a notation to a</b></p> <p>7 <b>certain study and I requested it. I don't recall with</b></p> <p>8 <b>this.</b></p> <p>9 Q. Do you know, sitting here today, whether you</p> <p>10 asked for any additional records to help inform your</p> <p>11 opinions with respect to Mrs. Alonso's case?</p> <p>12 <b>A. I can't say specifically to Mrs. Alonso. I</b></p> <p>13 <b>had requested further records of other doctors. It</b></p> <p>14 <b>mentions there would be clinic notes, but it mentioned I</b></p> <p>15 <b>saw Dr. So-and-so. And I didn't have that, so I'd</b></p> <p>16 <b>request it. I cannot say in, actually, Ms. Alonso I did</b></p> <p>17 <b>that, though.</b></p> <p>18 Q. Did -- did you review, in their entirety, all</p> <p>19 of the records listed here on pages 2 and 3 of Exhibit C</p> <p>20 to your report?</p> <p>21 <b>A. Yes. And I believe with Ms. Alonso that came</b></p> <p>22 <b>out to something like 1925 pages.</b></p> <p>23 Q. And you reviewed every page?</p> <p>24 <b>A. Yes, I did.</b></p> <p>25 Q. And how about the deposition transcripts that</p>	<p style="text-align: right;">Page 488</p> <p>1 Q. Thank you. For some reason, that</p> <p>2 pronunciation is going to give me trouble all day, so</p> <p>3 I'm going to write it down.</p> <p>4 And my understanding, Doctor, from reviewing</p> <p>5 your reports in those three plaintiffs' cases, is that</p> <p>6 you saw all three women on the same day; is that right?</p> <p>7 <b>A. Correct, on October 4th, 2014.</b></p> <p>8 Q. And where did those IMEs take place?</p> <p>9 <b>A. Nashville.</b></p> <p>10 Q. Nashville, Tennessee?</p> <p>11 <b>A. Correct.</b></p> <p>12 Q. Why Nashville, Tennessee?</p> <p>13 <b>A. That's -- that's where I was told they were</b></p> <p>14 <b>being arranged.</b></p> <p>15 Q. Who -- strike that.</p> <p>16 At what facility in Nashville, Tennessee?</p> <p>17 <b>A. It was a -- there is an OB/GYN office that it</b></p> <p>18 <b>was taken place in. If you would like the exact</b></p> <p>19 <b>address, I could give that to you.</b></p> <p>20 Q. It was a doctor's office?</p> <p>21 <b>A. Correct.</b></p> <p>22 Q. Do you know the name of the OB/GYN or the name</p> <p>23 of the practice?</p> <p>24 <b>A. I don't know the name of whose office it is.</b></p> <p>25 <b>It was Legacy OB/GYN of Tennessee, actually, in Smyrna,</b></p>



<p style="text-align: right;">Page 489</p> <p><b>1 which is, S-M-Y-R-N-A, which is a suburb in Nashville.</b></p> <p>2 Q. You told me yesterday that you bill for your</p> <p>3 time at the rate of \$700 an hour; is that right?</p> <p>4 <b>A. That is correct.</b></p> <p>5 Q. So did you bill for your travel to Nashville,</p> <p>6 Tennessee, to perform the IMEs?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. And that was at the 700-dollar-an-hour rate?</p> <p>9 <b>A. Correct. Everything I do is at \$700 an hour.</b></p> <p>10 Q. Okay. So, for all three cases, however much</p> <p>11 time you spent doing the IME, that was at the</p> <p>12 700-hundred-dollar-an-hour rate?</p> <p>13 <b>A. That is correct.</b></p> <p>14 Q. And then your return travel to Minnesota was</p> <p>15 at the same rate?</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. How much time did you spend with Mrs. Alonso?</p> <p>18 <b>A. Each -- each individual face-to-face time was,</b></p> <p>19 <b>roughly, 45 minutes, but that's not counting, obviously,</b></p> <p>20 <b>the time reviewing the records and things, but</b></p> <p>21 <b>face-to-face time and exam.</b></p> <p>22 Q. So that's the same, roughly, 45 minutes for</p> <p>23 Mrs. Wheeler and Mrs. Bolyard?</p> <p>24 <b>A. That is an estimate, a fairly accurate</b></p> <p>25 <b>estimate. I can't say exactly 45 minutes with each one.</b></p>	<p style="text-align: right;">Page 491</p> <p><b>1 an operative note. So, again, there is no correlation</b></p> <p><b>2 between volume and time. So I can't answer that</b></p> <p><b>3 question.</b></p> <p>4 BY MS. GEIST:</p> <p>5 Q. Well, would you agree with me that</p> <p>6 Mrs. Bolyard has a more extensive and complex medical</p> <p>7 history than Mrs. Alonso and Mrs. Wheeler?</p> <p>8 <b>A. I think her past medical history is more</b></p> <p><b>9 complicated. I deal with this on a daily basis in my</b></p> <p><b>10 practice. So as far as complicated, they're all</b></p> <p><b>11 complicated.</b></p> <p>12 Q. Did you need to conduct the IMEs in order to</p> <p>13 reach the opinions in Mrs. Alonso's case and</p> <p>14 Mrs. Wheeler's case and Mrs. Bolyard's case?</p> <p>15 <b>A. Oh, I think it's essential. In this type of</b></p> <p><b>16 thing, you have to be able to do an exam. It's not like</b></p> <p><b>17 you can do a blood test or an X-ray to know. You have</b></p> <p><b>18 to actually do a physical exam. And much to the</b></p> <p><b>19 patient's chagrin, you have to also do a pelvic exam.</b></p> <p>20 <b>And so, yes, in my opinion, my strong opinion,</b></p> <p><b>21 it was essential to do an exam. Without an exam, you</b></p> <p><b>22 can't make an accurate diagnosis.</b></p> <p>23 Q. So you couldn't make an accurate diagnosis or</p> <p>24 formulate your opinions in any of the cases without</p> <p>25 conducting the IME; is that what you're telling me?</p>
<p style="text-align: right;">Page 490</p> <p><b>1 Some were a little bit more. Some were a little bit</b></p> <p><b>2 less.</b></p> <p>3 Q. Do you remember who took the longest of the</p> <p>4 three plaintiffs?</p> <p>5 <b>A. I do not recall.</b></p> <p>6 Q. Do you remember whether you had to spend more</p> <p>7 time with Mrs. Alonso compared to Mrs. Wheeler compared</p> <p>8 to Mrs. Bolyard?</p> <p>9 <b>A. I do not recall any of them taking more or</b></p> <p><b>10 less time. I was not focused on that. Reviewing their</b></p> <p><b>11 medical records at times could take considerably more,</b></p> <p><b>12 considerably less, depending upon the volume of records.</b></p> <p>13 Q. The volume of records for each of these</p> <p>14 plaintiffs is different. Fair summary?</p> <p>15 <b>A. That's correct.</b></p> <p>16 Q. Mrs. Bolyard, for example, has a more</p> <p>17 extensive and complicated medical history than</p> <p>18 Mrs. Alonso and Mrs. Wheeler?</p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 <b>A. I can't necessarily say. The volume of</b></p> <p><b>22 records does not correlate to the complexity. Sometimes</b></p> <p><b>23 I would be provided 200 pages of nursing notes which had</b></p> <p><b>24 very little material to it, but it took time and pages.</b></p> <p>25 <b>Sometimes I would spend an hour or two on one page like</b></p>	<p style="text-align: right;">Page 492</p> <p>1 MS. GAYLE: Object to form.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. No. What I'm saying is, I can review the</b></p> <p><b>4 outside records, review the other individual's exams,</b></p> <p><b>5 formulate somewhat of an opinion of what other people</b></p> <p><b>6 think. However, I'm going to keep an open mind because,</b></p> <p><b>7 in my practice, where I practice at the tertiary care</b></p> <p><b>8 center, I'm always keeping an open mind and I have to do</b></p> <p><b>9 an exam to prove it for myself. I do this daily. So</b></p> <p><b>10 it's not like an individual who might not see this very</b></p> <p><b>11 often.</b></p> <p>12 <b>So the IME would be further -- the physical</b></p> <p><b>13 exam, the interaction with the individual, talking to</b></p> <p><b>14 them is a major part of coming to a conclusion, but it's</b></p> <p><b>15 not everything.</b></p> <p>16 Q. But you're not going to reach your final</p> <p>17 conclusion and analysis until you do that IME, correct?</p> <p>18 MS. GAYLE: Objection. Asked and answered.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. No. I would say that I will form ideas,</b></p> <p><b>21 concepts, and a differential diagnosis based upon the</b></p> <p><b>22 medical records and then determine if my physical exam</b></p> <p><b>23 agrees or disagrees with what others had said.</b></p> <p>24 Q. So you told me that you did the IME for the</p> <p>25 three plaintiffs on October 14th, 2014, correct?</p>



<p style="text-align: right;">Page 493</p> <p>1 <b>A. October 4th.</b></p> <p>2 Q. I thought you said October 14th. Is it the</p> <p>3 4th?</p> <p>4 <b>A. I'm going off of -- I don't recall exactly</b></p> <p>5 <b>which day. I have to go off of what I wrote down here.</b></p> <p>6 <b>And I have written down here October 4th. I would have</b></p> <p>7 <b>to go through whatever date I state in here is the date.</b></p> <p>8 <b>Because on page 4 of Alonso, I say October 4th. Yeah, I</b></p> <p>9 <b>say -- yeah, it's October 4th.</b></p> <p>10 Q. Okay. That's fine. I thought you told me</p> <p>11 October 14th, which is why I was asking you.</p> <p>12 <b>A. I may have said that. That would be</b></p> <p>13 <b>incorrect. October 4th is the correct date.</b></p> <p>14 Q. So my question is, so you performed your IME</p> <p>15 before you signed your expert reports in each of the</p> <p>16 three cases?</p> <p>17 <b>A. That is correct.</b></p> <p>18 Q. And Mrs. Alonso's report is dated October 9th,</p> <p>19 2014, correct?</p> <p>20 <b>A. That is correct.</b></p> <p>21 Q. And that's your signature there, Dr. Elliott?</p> <p>22 <b>A. That is an electronic signature, yes.</b></p> <p>23 Q. Okay. But this is a true copy of your expert</p> <p>24 report in the case, correct --</p> <p>25 <b>A. That is correct.</b></p>	<p style="text-align: right;">Page 495</p> <p>1 <b>taking, it was just myself and the patient. No one else</b></p> <p>2 <b>was in the room. I did not allow anybody in the room.</b></p> <p>3 Q. Did you have a nurse or a physician's</p> <p>4 assistant or anybody like that?</p> <p>5 <b>A. For just the hyst- --</b></p> <p>6 MS. GAYLE: Excuse me. Just let him finish the</p> <p>7 question so y'all don't talk over each other.</p> <p>8 MS. GEIST: Sure.</p> <p>9 MS. GAYLE: -- for the court reporter's sake.</p> <p>10 MS. GEIST: No. I apologize.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. For just the history taking, confirmation of</b></p> <p>13 <b>what I had reviewed with the patient, I mean, as far as</b></p> <p>14 <b>medical records, I went over my medical records, my</b></p> <p>15 <b>notes, asked the patient did this correlate, did they</b></p> <p>16 <b>agree with this? That was just myself and the patient.</b></p> <p>17 <b>That --</b></p> <p>18 Q. So --</p> <p>19 <b>A. I'll finish.</b></p> <p>20 Q. I'm sorry. I'm sorry. I thought you were</p> <p>21 done.</p> <p>22 <b>A. That's all right. Then when it came to the</b></p> <p>23 <b>physical exam, there was a nurse present to act as a</b></p> <p>24 <b>chaperone when I did just the physical exam. So I would</b></p> <p>25 <b>exit the room. The nurse would come in. This was an</b></p>
<p style="text-align: right;">Page 494</p> <p>1 Q. -- as you flip through it?</p> <p>2 Did any of your opinions, with respect to</p> <p>3 Mrs. Alonso, change after you performed the IME?</p> <p>4 <b>A. Not that I recall, no, not specifically.</b></p> <p>5 <b>Because of what I do on a daily basis, as far as where I</b></p> <p>6 <b>work, and I'm used to dealing with this, I'm looking for</b></p> <p>7 <b>things that weren't necessarily examined before, like</b></p> <p>8 <b>pain over the buttock where obturator -- where the mesh</b></p> <p>9 <b>arms could be obturator pain, adductor pain, abductor</b></p> <p>10 <b>pain, A-B-D-U-C-T-O-R-S.</b></p> <p>11 <b>On the physical exam, I'm specifically</b></p> <p>12 <b>touching where -- inside the vagina on the midportion.</b></p> <p>13 <b>So, again, I have an idea because of what I do all of</b></p> <p>14 <b>the time of what the diagnosis could be. But, again, I</b></p> <p>15 <b>would say it augmented my knowledge of the patient.</b></p> <p>16 Q. So you don't recall, with respect to</p> <p>17 Mrs. Alonso's case or Mrs. Wheeler's case or</p> <p>18 Mrs. Bolyard's case, whether you needed to amend or</p> <p>19 change your initial opinions that you formed about each</p> <p>20 of the cases after the IME was conducted?</p> <p>21 <b>A. I don't recall doing that on either -- any of</b></p> <p>22 <b>these three individuals.</b></p> <p>23 Q. Who was present during the IMEs that you</p> <p>24 performed for each of the plaintiffs?</p> <p>25 <b>A. For the interaction, the initial history</b></p>	<p style="text-align: right;">Page 496</p> <p>1 <b>employee of the OB/GYN clinic. I did not -- I had never</b></p> <p>2 <b>met her before. She would get the patient ready. I</b></p> <p>3 <b>would come back and then I would do the physical exam</b></p> <p>4 <b>with the nurse there. I would exit. The nurse would</b></p> <p>5 <b>get the patient dressed. I would come back, go over a</b></p> <p>6 <b>few things, and that was it.</b></p> <p>7 Q. Are you finished?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. I apologize. Sometimes I jump in a little too</p> <p>10 quickly.</p> <p>11 <b>A. No worries.</b></p> <p>12 Q. Were there any lawyers present at any time</p> <p>13 during any of your IMEs of each of the three plaintiffs?</p> <p>14 <b>A. I cannot speak if they had been out in the</b></p> <p>15 <b>waiting room. I did not see anybody. I did not allow</b></p> <p>16 <b>anyone in the room, no family members. There was only</b></p> <p>17 <b>one time that a family member requested to come back. I</b></p> <p>18 <b>told them, no, and I don't know if it was on this one or</b></p> <p>19 <b>not. It could have been on another individual. So</b></p> <p>20 <b>bottom line, no. I didn't see anybody.</b></p> <p>21 Q. So, during the time that you took an initial</p> <p>22 history, there wasn't any other person in the room other</p> <p>23 than you and the plaintiff, correct?</p> <p>24 <b>A. At all times, for all individuals, I was the</b></p> <p>25 <b>only one there with the patient alone.</b></p>

In Re: CR Bard 200

Daniel Elliott M.D., Vol. II

11/16/2014

<p style="text-align: right;">Page 497</p> <p>1 Q. And during the actual pelvic and vaginal exam 2 portion of the IME, were there any other physicians 3 present? 4 <b>A. No. It was only, at all times for all three</b> 5 <b>individuals, when it came time for the physical exam,</b> 6 <b>there was just myself, the patient, and the nurse. That</b> 7 <b>was it.</b> 8 Q. Did you -- were there any other plaintiffs' 9 experts there at the OB/GYN facility on the same day 10 examining women? 11 <b>A. No.</b> 12 Q. Did you examine any other women on that day 13 other than Mrs. Alonso, Mrs. Wheeler, Mrs. Bolyard who 14 have lawsuits against Bard? 15 MS. GAYLE: Object to form. And I'm going to ask 16 that you not answer that. We're not here to talk about 17 any other plaintiffs in this litigation except these 18 three ladies. 19 MS. GEIST: So you're instructing the witness not 20 to answer? 21 MS. GAYLE: I don't think that it's relevant, 22 Counsel. 23 MS. GEIST: I'm just trying to understand your 24 position. 25</p>	<p style="text-align: right;">Page 499</p> <p>1 <b>on. I brought that in with my yellow notepad. I took</b> 2 <b>notes. And immediately, at the finish of the IME, I go</b> 3 <b>out. I would put them into an iPad, and then I had the</b> 4 <b>notes shredded. So the actual handwritten notes are</b> 5 <b>gone.</b> 6 Q. So you actually took down information that 7 each of the plaintiffs provided to you on a yellow 8 notepad, correct? 9 <b>A. Correct.</b> 10 Q. And then, after you obtained that information, 11 you put some of it into an iPad? 12 <b>A. Correct, into -- into a Word document so that</b> 13 <b>it was legible, understandable, because I take a lot of</b> 14 <b>notes. There could be arrows pointed everywhere. I</b> 15 <b>make it organized so it's not forgotten, immediately put</b> 16 <b>it into a document labeled that specific patient so</b> 17 <b>there is no mistake on the individual, and then get rid</b> 18 <b>of the paper copy.</b> 19 Q. And so that was a Word document you're 20 describing? 21 <b>A. A Word document saved in Dropbox so it would</b> 22 <b>not be lost, yes.</b> 23 Q. You said you shredded the yellow notepad where 24 you took the notes regarding all three women? 25 <b>A. Correct. For confidentiality purposes, the</b></p>
<p style="text-align: right;">Page 498</p> <p>1 BY MS. GEIST: 2 Q. Did you examine any other women for whom you 3 did not provide an expert report? 4 <b>A. No.</b> 5 Q. Did you spend any time with any of the three 6 plaintiffs after the IME? 7 <b>A. No. Once I was done with it, no. After that,</b> 8 <b>they left.</b> 9 Q. Dr. Elliott, you told me that initially you 10 had a conversation with each of the three plaintiffs and 11 you took a history; is that right? 12 <b>A. Correct.</b> 13 Q. Did you have them fill out any documents, any 14 forms? 15 <b>A. No.</b> 16 Q. Did they fill out any paperwork at any point 17 in time during the IME? 18 <b>A. No.</b> 19 Q. So where did you record the history and 20 information that you were provided from each of the 21 plaintiffs? 22 <b>A. I had a notepad, a yellow legal notepad.</b> 23 Q. And where is that notepad? 24 <b>A. I took notes. I had -- I had my printout of</b> 25 <b>the medical records that I took just the generic notes</b></p>	<p style="text-align: right;">Page 500</p> <p>1 <b>handwritten notes -- not that anyone would be able to</b> 2 <b>read my writing -- but the handwritten notes were</b> 3 <b>shredded.</b> 4 Q. Is there any information that was contained on 5 the yellow notepad that was not put into the Word 6 document? 7 <b>A. No. Essentially, everything was transferred</b> 8 <b>over to just a digital copy is all.</b> 9 Q. Did anybody ever tell you that you needed to 10 preserve information with respect to your IME of the 11 three plaintiffs? 12 MS. GAYLE: Object to form. He did preserve this 13 information. 14 BY THE WITNESS: 15 <b>A. Yeah. All of the information was preserved.</b> 16 <b>It was put into a logical, legible way. A doctor's</b> 17 <b>handwriting, as you know, tends to be scattered. There</b> 18 <b>are arrows transferred all around, so I wanted to make</b> 19 <b>sure immediately after coming out of the room, when it</b> 20 <b>was fresh in my mind, I put it into a legible, logical</b> 21 <b>document.</b> 22 Q. And do you have access to that Word document 23 now? 24 <b>A. No. All of those documents then were put into</b> 25 <b>my physical exam notes. My history notes were then put</b></p>

<p style="text-align: right;">Page 501</p> <p>1 <b>into the IME, and so they were all just transferred all</b></p> <p>2 <b>over.</b></p> <p>3 Q. So do you still have that Word document,</p> <p>4 though, for each plaintiff?</p> <p>5 <b>A. Those documents are gone because I don't keep</b></p> <p>6 <b>them because then it gets confusing which document is</b></p> <p>7 <b>what. So I transferred all of those into my IME, get</b></p> <p>8 <b>rid of the old documents, and then I would have this as</b></p> <p>9 <b>my official document.</b></p> <p>10 Q. So if we look at Mrs. Alonso's report</p> <p>11 beginning on page 4 where it begins, On October 4th,</p> <p>12 2014, in Nashville, Tennessee, I personally examined</p> <p>13 Mrs. Alonso?</p> <p>14 <b>A. That is correct.</b></p> <p>15 Q. Do the notes or the information provided here,</p> <p>16 is that what came from your Word document which came</p> <p>17 from your yellow notepad?</p> <p>18 <b>A. Yes.</b></p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 <b>A. That is correct.</b></p> <p>22 Q. Is there anything that you recorded on the</p> <p>23 yellow notepad or in the Word document that is not</p> <p>24 contained here in the expert report?</p> <p>25 <b>A. To the best of my knowledge, this is it.</b></p>	<p style="text-align: right;">Page 503</p> <p>1 Q. And that document no longer exists?</p> <p>2 <b>A. Correct.</b></p> <p>3 Q. And neither does the yellow notepad?</p> <p>4 <b>A. Correct.</b></p> <p>5 Q. So where, in your report, is all of the</p> <p>6 information that you recorded during the IME?</p> <p>7 <b>A. It is recorded in, as far as me going through</b></p> <p>8 <b>the history, there will be parts of it in there for</b></p> <p>9 <b>clarification of dates or feelings, pain, et cetera.</b></p> <p>10 <b>And then, if you go to page 4, really start at the very</b></p> <p>11 <b>top where it says, Currently, Mrs. Alonso is not</b></p> <p>12 <b>sexually active due to pain, that would probably be</b></p> <p>13 <b>where it actually started. Because currently to me</b></p> <p>14 <b>means as of that date, October 4th. And so, when you</b></p> <p>15 <b>see a Visual Analog Pain Scale, that is my records, my</b></p> <p>16 <b>input.</b></p> <p>17 Q. Is there anywhere else in the report where the</p> <p>18 information you obtained via the IME could be found?</p> <p>19 <b>A. Well, in the diagnoses, the physical exam,</b></p> <p>20 <b>which is that part here, the differential diagnosis, all</b></p> <p>21 <b>of those things.</b></p> <p>22 Q. Can you be sure, sitting here today, Doctor,</p> <p>23 that every word and information piece you took down</p> <p>24 during the IME and recorded on your yellow notepad and</p> <p>25 put into a Word document is contained here in the expert</p>
<p style="text-align: right;">Page 502</p> <p>1 Q. Are you sure about that?</p> <p>2 <b>A. I just said, to the best of my knowledge, this</b></p> <p>3 <b>is it.</b></p> <p>4 Q. And did you say to me that you deleted the</p> <p>5 Word document after it was prepared by you?</p> <p>6 <b>A. Yeah. Because it goes all into this note, so</b></p> <p>7 <b>there is no reason to keep two documents.</b></p> <p>8 Q. There is no way of retrieving that document</p> <p>9 now?</p> <p>10 MS. GAYLE: Just, Counsel, so you're clear, you're</p> <p>11 asking him to look at a certain section, but then your</p> <p>12 next question was with regard to the case-specific</p> <p>13 expert report. And so, just so y'all are both on the</p> <p>14 same page and I'm not confused, are you talking about</p> <p>15 that one particular section or that -- or the entire</p> <p>16 report? I'm confused.</p> <p>17 MS. GEIST: Well, yeah. Sure.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. You tell me, Dr. Elliott, if you can. You</p> <p>20 told me you recorded certain information on a yellow</p> <p>21 notepad, and then you took that information and you put</p> <p>22 it in a Word document for Mrs. Alonso, correct?</p> <p>23 <b>A. Correct.</b></p> <p>24 Q. And it was actually labeled Rosaida Alonso?</p> <p>25 <b>A. Correct.</b></p>	<p style="text-align: right;">Page 504</p> <p>1 report for Mrs. Alonso?</p> <p>2 <b>A. To the best of my knowledge, it is. There</b></p> <p>3 <b>would be no reason to delete or remove anything. All</b></p> <p>4 <b>the notepad and the Word document are for clarification,</b></p> <p>5 <b>legibility. And if I see a large number of individuals,</b></p> <p>6 <b>as per my habit to keep things organized, I immediately</b></p> <p>7 <b>take care of it at that point in time so, again, it's</b></p> <p>8 <b>logical so I don't get anything -- make any mistakes.</b></p> <p>9 Q. During your review of the medical records for</p> <p>10 Mrs. Alonso, did you take notes as you went through and</p> <p>11 reviewed those records?</p> <p>12 <b>A. Yes.</b></p> <p>13 Q. Where are those notes?</p> <p>14 <b>A. Those notes are in here.</b></p> <p>15 Q. Well, how did you -- how did you take them</p> <p>16 when you initially looked at the records? What was</p> <p>17 your -- what was your method?</p> <p>18 <b>A. I go through and, as I make a note of it, like</b></p> <p>19 <b>I find -- I document the -- I document the document that</b></p> <p>20 <b>I was reviewing, which is in the reliance list. I'll</b></p> <p>21 <b>take notes as far as the date of surgery. I'll take</b></p> <p>22 <b>quotes out of the operative note, doctor's comments,</b></p> <p>23 <b>those types of things.</b></p> <p>24 Q. So just so I understand, so when you're</p> <p>25 reviewing the medical records, do you actually highlight</p>

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<p style="text-align: right;">Page 505</p> <p>1 or put comments or do anything to the records 2 themselves? 3 <b>A. No.</b> 4 Q. Do you take handwritten notes? 5 <b>A. Handwritten or electronic notes.</b> 6 Q. So do you have handwritten notes somewhere 7 relating to your review of medical records for 8 Mrs. Alonso? 9 <b>A. No. Handwritten notes are taken initially.</b> 10 <b>Everything I convert over to electronic. Handwritten</b> 11 <b>notes are just for -- because the medical records I get</b> 12 <b>don't necessarily come in any sequence, chronologic</b> 13 <b>sequence. So it's very difficult. I get one year, a</b> 14 <b>next year, and then they're flopped back and forth. So</b> 15 <b>handwritten notes sometimes are just easier to take to</b> 16 <b>start off with and then I convert that to electronic.</b> 17 Q. And did you also destroy any handwritten 18 notes you took with respect to the records of 19 Mrs. Alonso? 20 MS. GAYLE: Object to form. Mischaracterizes his 21 testimony. 22 BY MS. GEIST: 23 Q. Did you get rid of those notes? 24 MS. GAYLE: Object to form. 25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 507</p> <p>1 BY THE WITNESS: 2 <b>A. I took -- yeah, I took notation of it, yeah,</b> 3 <b>so of a chronologic sequence, which then I put into the</b> 4 <b>records here.</b> 5 Q. And where is the chronologic sequence or other 6 notes that you took with respect to the medical records 7 for Mrs. Alonso, Mrs. Wheeler, and Mrs. Bolyard? 8 <b>A. I have a Dropbox account they would be in.</b> 9 Q. So is that information accessible and 10 available now? 11 <b>A. I would be able to get access to it, yes.</b> 12 MS. GEIST: So I'll just make a formal demand and 13 request for that information we just discussed, which is 14 Dr. Elliott's electronic notes regarding his review of 15 the medical records of Mrs. Alonso and Mrs. Wheeler and 16 Mrs. Bolyard. 17 BY MS. GEIST: 18 Q. Did -- other than your communications with 19 counsel in this litigation, did you speak with anyone 20 else with respect to your opinions about Mrs. Alonso, 21 Mrs. Wheeler, and Mrs. Bolyard? 22 <b>A. No.</b> 23 Q. Did you talk to any other medical doctors or 24 experts for plaintiffs in the litigation about your 25 opinions?</p>
<p style="text-align: right;">Page 506</p> <p>1 <b>A. Well, those notes are all converted into</b> 2 <b>electronic digital form.</b> 3 Q. So did you get rid of the written notes? 4 <b>A. So the written notes are gone, yes.</b> 5 Q. Same -- same method for Mrs. Wheeler and 6 Mrs. Bolyard? Did you take written notes and then now 7 they're gone? 8 MS. GAYLE: Object to form. 9 BY THE WITNESS: 10 <b>A. Yeah. I can't speak to all of them. I mean,</b> 11 <b>again, there is, you know, 11,000 -- 1100 pages. I told</b> 12 <b>you 1900 for Alonso. I can't say what I did with each</b> 13 <b>one. I didn't keep that kind of a record of what I did</b> 14 <b>as far as records go, I mean, handwritten notes or not.</b> 15 <b>I put Post-It notes on things to come back to it, but I</b> 16 <b>don't save Post-It notes.</b> 17 Q. Those Post-It notes are not available to us 18 now either, are they? 19 <b>A. No. They're not available to me either. I</b> 20 <b>don't have them.</b> 21 Q. Did you create separate Word documents or some 22 other electronic memorialization when you went through 23 the medical records for Mrs. Alonso, Mrs. Wheeler, and 24 Mrs. Bolyard? 25 MS. GAYLE: Object to form.</p>	<p style="text-align: right;">Page 508</p> <p>1 <b>A. No.</b> 2 Q. Dr. Elliott, if you look with me at your 3 report for Mrs. Alonso -- 4 <b>A. Yes.</b> 5 Q. -- do you have that in front of you? 6 <b>A. Yes, I do.</b> 7 Q. Is that your -- is that your own copy? 8 <b>A. This is my own highlighted copy, yes. With no</b> 9 <b>notes on it, but it is highlighted.</b> 10 Q. Well, that was my next question. Do you have 11 any handwritten notes on that copy? 12 <b>A. Yeah. The only thing is, as I was going</b> 13 <b>through it -- yeah. I have one note indicating, on page</b> 14 <b>6, there is an accidental duplication. I duplicated</b> 15 <b>what was said twice. I just noticed that.</b> 16 Q. Okay. 17 <b>A. So other --</b> 18 Q. From page 6 to 7, and I noticed that as 19 well -- 20 <b>A. Yeah.</b> 21 Q. -- it's a pure duplication? 22 <b>A. That is -- that is correct. Otherwise, they</b> 23 <b>are highlighted, dates are circled so I can find them</b> 24 <b>easier. That appears to be it. And I think -- and then</b> 25 <b>I noticed a typographical error on page 11. I put -- I</b></p>

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<p style="text-align: right;">Page 509</p> <p>1 <b>accidentally put the Cook device down on the last</b>  2 <b>paragraph instead of the Bard device. That's a</b>  3 <b>typographical error.</b>  4 Q. Did you notice any other errors or  5 inaccuracies in your report that we need to change here  6 today?  7 <b>A. Let me go through it page by page to make</b>  8 <b>sure.</b>  9 Q. Sure.  10 <b>A. Not that I see on this.</b>  11 Q. Doctor, you can feel free to review and refer  12 to that version of your report as I ask you questions  13 about it. But I'm just going to mark it as an exhibit  14 to your deposition if that's okay with you.  15 <b>A. Sure. That is perfectly fine.</b>  16 Q. Thank you. Now, we can toss documents at one  17 another.  18 (Elliott Deposition Exhibit No. 30  19 was marked for identification.)  20 BY MS. GEIST:  21 Q. And that will be, for the record, Exhibit 30,  22 which is Dr. Elliott's copy of his report for  23 Mrs. Alonso with some highlighting and handwritten  24 notes.  25 MS. GAYLE: And, Counsel, I haven't seen that</p>	<p style="text-align: right;">Page 511</p> <p>1 MS. GEIST: For the record, we just took a break  2 and counsel and I both agreed that Exhibit 30 appears to  3 be a draft of Dr. Elliott's report and was not the  4 doctor's version of the final report. So, for the  5 record, Exhibit 30 is being withdrawn and not being put  6 into evidence.  7 MS. GAYLE: Thank you, Counsel.  8 MS. GEIST: Thank you.  9 BY MS. GEIST:  10 Q. Doctor, you have what we've marked as Exhibit  11 29, which is your final report, correct?  12 <b>A. That is correct.</b>  13 Q. And you've added some highlights to that  14 report for efficiency purposes and to help us move along  15 quickly with respect to dates and other information?  16 <b>A. Correct.</b>  17 Q. Okay. I had started to ask you about the  18 error, the typo you noted on page 11?  19 <b>A. Yes.</b>  20 Q. And you said that's the Cook device and SIS  21 sling?  22 <b>A. SIS mesh sling, that's correct.</b>  23 Q. Are you -- are you involved in litigation on  24 behalf of the plaintiffs against that company?  25 <b>A. Yes, I am.</b></p>
<p style="text-align: right;">Page 510</p> <p>1 myself, so...  2 MS. GEIST: You didn't? Now, let me just show it  3 to you, and I'm going to look through it quickly.  4 BY MS. GEIST:  5 Q. You said, Doctor, that, on the last page of  6 your report, you had a typo on page 11. And that  7 sentence reads, Mrs. Alonso was unable to make a fully  8 informed decision about having the Cook device  9 implanted?  10 <b>A. Correct.</b>  11 Q. And you said that should read the Bard device?  12 <b>A. Correct.</b>  13 Q. What's the Cook device?  14 <b>A. Cook device is an SIS sling made of collagen,</b>  15 <b>porcine collagen.</b>  16 Q. And who manufactures that product?  17 <b>A. Cook.</b>  18 MS. GAYLE: Counsel, could we go off record just  19 for a second?  20 MS. GEIST: Sure.  21 VIDEO TECHNICIAN: We're off the record. The time  22 is 9:33 a.m.  23 (A recess was had.)  24 VIDEO TECHNICIAN: We're back on the record. The  25 time is 9:42 a.m.</p>	<p style="text-align: right;">Page 512</p> <p>1 Q. And have you provided any expert reports in  2 that litigation?  3 <b>A. Yeah. Yes.</b>  4 Q. Have you provided any deposition testimony in  5 that litigation?  6 <b>A. No.</b>  7 Q. Are you scheduled for deposition in that  8 litigation?  9 <b>A. Yes.</b>  10 Q. When is that going to take place?  11 <b>A. January 3rd.</b>  12 Q. January 3rd of 2015?  13 <b>A. Correct.</b>  14 Q. In this case, Doctor, Mrs. Alonso was also  15 implanted with the Align sling, correct?  16 <b>A. That is correct.</b>  17 Q. Okay.  18 <b>A. She had two surgeries at the same time.</b>  19 Q. And I understand, from your report and your  20 testimony yesterday, that you are not offering any  21 opinions with respect to the Bard Align sling; is that  22 correct?  23 <b>A. Well, unless I'm asked. I'm not here to talk</b>  24 <b>about the Align sling. This individual had the product</b>  25 <b>implanted. If you ask me about it, I will answer.</b></p>



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<p style="text-align: right;">Page 513</p> <p>1 Q. In your report, you're not providing any 2 opinions with respect to the Bard Align sling, correct? 3 MS. GAYLE: Objection. Form. 4 BY MS. GEIST: 5 Q. Is there any -- well, let me fix it. 6 Is there any opinion in your report for 7 Mrs. Alonso with respect to the Bard Align sling 8 product? 9 A. Not specifically. The problem comes that 10 she's had two products that are placed in the same 11 region. They're made out of the same type of mesh. And 12 so there's going to be complications overlying that. I 13 am here for the Avaulta product. But she has two 14 products that were placed in her. 15 Q. Understood. But you haven't reached any 16 opinions, to a reasonable degree of medical certainty, 17 that Mrs. Alonso's Bard Align sling caused her any 18 complications; is that correct? 19 MS. GAYLE: Object to form. Mischaracterizes 20 testimony. 21 BY THE WITNESS: 22 A. Well, no, that wouldn't necessarily be 23 correct, again, because we have a polypropylene mesh, 24 heavyweight that's put into the obturator foramen, this 25 exact same location as the Avaulta arms. And so that</p>	<p style="text-align: right;">Page 515</p> <p>1 problems. However, the Align sling could be a 2 contributing factor to it. Because if the Avaulta mesh 3 gets infected, the Avaulta POP mesh gets infected, she 4 also has the other mesh there which is going to get 5 infected. So it becomes complicated. 6 My opinion, as I outline in here, that the 7 inciting event, the culprit which causes the problems, 8 was the Avaulta mesh. 9 BY MS. GEIST: 10 Q. And not the Align sling? 11 MS. GAYLE: Object to form. 12 BY MS. GEIST: 13 Q. Is that correct? 14 A. Based upon statistics and my experience and 15 review of the literature, more likely than not it is the 16 Avaulta mesh that caused the problem and not the Align 17 sling. 18 Q. Thank you. Okay. So, Doctor, what I've tried 19 to do is summarize, as best I can, from looking at your 20 report, your opinions with respect to Mrs. Alonso. 21 Okay. So if you look at beginning on page 5 of your 22 report and then continuing on to page 6 -- 23 A. Yes. 24 Q. And just let me know, is this a fair summary 25 of your opinions, that Mrs. Alonso has experienced</p>
<p style="text-align: right;">Page 514</p> <p>1 makes it quite complicated. I have two large pieces of 2 mesh going to the same region. So I -- I can't state 3 that. I can state what I've stated in my report. 4 Q. Well, in your report, unless I'm missing it 5 somewhere, you attribute the complications and problems 6 that Mrs. Alonso describes to the Avaulta product, true? 7 A. It is my opinion of going through the -- all 8 that's happened with her, look at the differential 9 diagnosis, looking at the literature out there, 10 statistics and my experience, that, in her situation, it 11 was the Avaulta mesh -- excuse me, the Avaulta POP mesh 12 which is creating her problem. 13 Q. Okay. So that's just what I want to 14 understand. 15 A. Yeah. 16 Q. You're not going to give an opinion, in 17 Mrs. Alonso's case, that it was the Bard Align sling 18 that has caused her any problems or complications; is 19 that true? 20 MS. GAYLE: Object to form. 21 BY THE WITNESS: 22 A. No. I'm going off -- again, this is playing 23 the game of statistics of volume of mesh, what is more 24 likely. And more likely than not with medical 25 certainty, it is the Avaulta POP that caused her</p>	<p style="text-align: right;">Page 516</p> <p>1 pelvic pain, dyspareunia, urge incontinence, as well as 2 some long-term potential impacts due to the loss of 3 physical intimacy and that all of these problems and 4 complications are caused by the Bard Avaulta product? 5 MS. GAYLE: Object to form. 6 BY MS. GEIST: 7 Q. Is that a fair summary? 8 MS. GAYLE: Object to form. 9 BY THE WITNESS: 10 A. Yeah. Based upon my experience, my review of 11 the literature, attendance and giving lectures on the 12 international and national stage and review and the exam 13 of this patient and review of the records, as outlined 14 in my notes here, that is correct. 15 Q. Okay. So, at least the problems -- and I'm 16 trying to summarize so we can streamline a little bit. 17 The problems that we're talking about with respect to 18 Mrs. Alonso or the complications that you say are 19 attributed to the Bard Avaulta product are pelvic pain, 20 dyspareunia, urge incontinence, and then long-term 21 impact of lack of physical intimacy; is that correct? 22 MS. GAYLE: Object to form. 23 BY MS. GEIST: 24 Q. And then, Doctor, just so we're clear, on 25 pages 5 to 6, I'm looking at what you have numbered 1,</p>

<p style="text-align: right;">Page 517</p> <p>1 2, 3, and 4?</p> <p>2 <b>A. Yeah. Correct. No. I think that is, as I've</b></p> <p>3 <b>outlined here, I think that's a fair assessment.</b></p> <p>4 Q. Okay. And you -- tell me how you went about</p> <p>5 concluding that these four complications or problems</p> <p>6 that Mrs. Alonso alleges she's experiencing were caused</p> <p>7 by the Bard Avaulta product?</p> <p>8 <b>A. That's a fairly drawn-out process entailing,</b></p> <p>9 <b>you know, 21 years of medical experience, review of the</b></p> <p>10 <b>literature, examination of patients -- not just this</b></p> <p>11 <b>one, but in my career -- then review of her medical</b></p> <p>12 <b>records, review of all of the potential -- the</b></p> <p>13 <b>differential diagnosis of other factors that could be</b></p> <p>14 <b>contributing to it or not, and then putting them all</b></p> <p>15 <b>together, all factors, and coming up with this</b></p> <p>16 <b>diagnosis.</b></p> <p>17 Q. So did you do a differential diagnosis?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. Did you rule in any other medical problems or</p> <p>20 conditions that may have caused the complaints that</p> <p>21 Mrs. Alonso has and then rule them out?</p> <p>22 <b>A. Well, I approach each individual. Again, this</b></p> <p>23 <b>is because I work at a tertiary care center where we</b></p> <p>24 <b>have to keep an open mind of each individual coming in.</b></p> <p>25 <b>I do not disregard the outside doctor's opinions, but I</b></p>	<p style="text-align: right;">Page 519</p> <p>1 reaching your differential diagnosis for Mrs. Alonso?</p> <p>2 <b>A. Well, the list of potential differential</b></p> <p>3 <b>diagnoses in a female in this age group of pelvic</b></p> <p>4 <b>issues, you know, is probably a hundred different</b></p> <p>5 <b>things; MS, Parkinson's, myositis, endometriosis. Did I</b></p> <p>6 <b>go through, as you say, and list out all of those? I</b></p> <p>7 <b>did not. But those would go through -- that goes</b></p> <p>8 <b>through my thought process, and I do that on every</b></p> <p>9 <b>single patient that I do every single day in my work.</b></p> <p>10 Q. Okay. So just so I'm clear, there's</p> <p>11 nowhere -- if we look at your report, there is nowhere</p> <p>12 in your report that lists the other medical conditions</p> <p>13 or problems that you considered specifically for</p> <p>14 Mrs. Alonso and then ruled them out or concluded that</p> <p>15 they were not causing her pelvic pain, dyspareunia, urge</p> <p>16 incontinence?</p> <p>17 MS. GAYLE: Object to form.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A. I do not go through and list out the rare</b></p> <p>20 <b>issues of multiple sclerosis and endometriosis,</b></p> <p>21 <b>interstitial cystitis. I look at -- I think about those</b></p> <p>22 <b>things. I then look at the medical records to see if</b></p> <p>23 <b>there is any support for them. If I find support for</b></p> <p>24 <b>that possibility, then I will include that in there.</b></p> <p>25 <b>But I'm not going to list every possible thing.</b></p>
<p style="text-align: right;">Page 518</p> <p>1 always try and look at it with a critical eye. Do I</p> <p>2 agree or not?</p> <p>3 So as I went through the list and looked at</p> <p>4 her very carefully, looked at potential etiologies of</p> <p>5 neurologic disorders, preexisting neurologic disorders,</p> <p>6 which I'm not aware of any, any preexisting uterine or</p> <p>7 GYN chronic pain syndromes, endometriosis, pelvic floor</p> <p>8 myalgia, fibromyalgia, myositis, multiple sclerosis.</p> <p>9 The list is -- sounds infinite, but we have to, again,</p> <p>10 figure out all of the things that could be playing a</p> <p>11 role and then looking at her and her data, her medical</p> <p>12 records and her exam. And so I might not list all of my</p> <p>13 differential diagnoses, but those are all of the things</p> <p>14 that go through my thought process.</p> <p>15 Q. Okay. So would you agree with me that, when</p> <p>16 we look at your report for Mrs. Alonso, it doesn't tell</p> <p>17 us what you considered and ruled out in reaching your</p> <p>18 differential diagnosis?</p> <p>19 MS. GAYLE: Object to form. The report, he's</p> <p>20 already testified, contains his opinions. It's an</p> <p>21 unfair characterization of the evidence.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Well, does the report in any place, and you</p> <p>24 can point me to it, Dr. Elliott, if I'm missing it, does</p> <p>25 the report tell us what you ruled in or considered in</p>	<p style="text-align: right;">Page 520</p> <p>1 <b>Brain trauma, that can -- that can lead to it.</b></p> <p>2 <b>Spinal cord injury can lead to it. I do not put that in</b></p> <p>3 <b>there. But then, when I do my exam and I state</b></p> <p>4 <b>neurologically normal, then that, to me, my statement</b></p> <p>5 <b>neurologically normal, that rules out MS, Parkinson's,</b></p> <p>6 <b>spinal cord injury.</b></p> <p>7 Q. Understood, Doctor. And I'm not trying to be</p> <p>8 tricky about this. I just want to see if you agree with</p> <p>9 me that, if we look at your report, there is no place in</p> <p>10 the report that provides us with a list of what medical</p> <p>11 conditions or problems that you considered with respect</p> <p>12 to Mrs. Alonso when reaching your differential</p> <p>13 diagnosis. If there is some -- if it's in the report</p> <p>14 someplace and you can point it out to me, I would</p> <p>15 appreciate it.</p> <p>16 MS. GAYLE: Objection. Asked and answered.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A. The physical -- yeah, I mean, I've gone over</b></p> <p>19 <b>this several times now. The differential diagnosis that</b></p> <p>20 <b>I go through when I encounter a patient, initially, that</b></p> <p>21 <b>differential diagnosis, as I'm trained, should be</b></p> <p>22 <b>infinite. And then you very rapidly, through</b></p> <p>23 <b>experience, review of the medical literature, you can</b></p> <p>24 <b>narrow that differential diagnosis down rapidly. But do</b></p> <p>25 <b>I go through and list every possible thing? Again, MS,</b></p>



<p style="text-align: right;">Page 521</p> <p>1 <b>let's talk about that. To me, also, when I say</b>  2 <b>neurologic exam without gross deficit, that's going to</b>  3 <b>be excluding all of those things, and the same thing</b>  4 <b>with the abdominal exam, everything. So I don't go out</b>  5 <b>and list every possibility.</b>  6 Q. Is there a list in the report or a note about  7 anything, any medical condition you considered with  8 respect to Mrs. Alonso and you ruled it out, in  9 concluding that the Bard Avaulta mesh was the cause of  10 her injuries and problems she's complaining about?  11 MS. GAYLE: Objection. Asked and answered.  12 BY THE WITNESS:  13 A. Yeah. I think we're -- I mean, each time we  14 ask this, it's going to be the exact same answer. I do  15 not go through and list out every possibility of  16 differential diagnosis. Again, that list is infinite.  17 But in my experience and training, as I'm  18 going through the medical records, we're knocking each  19 one of those out. But I don't go through and write  20 those all out for you in a list. Again, that list is  21 too long.  22 BY MS. GEIST:  23 Q. Okay. So there is no list. You can agree  24 with me on that, there is no list here in the report?  25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 523</p> <p>1 all I'm asking for you is to answer my question, is  2 there a list in your report, yes or no? Can you answer  3 that question for me?  4 MS. GAYLE: Objection, counsel, argumentative.  5 BY MS. GEIST:  6 Q. Can you answer that question, Dr. Elliott?  7 MS. GAYLE: And object to form and asked and  8 answered.  9 BY THE WITNESS:  10 A. As I've said, when the judge asks me directly,  11 I can always answer him and I'll answer him in the exact  12 same way. A differential diagnosis is infinite to start  13 off with. To --  14 Q. Why won't you tell me that there is no list in  15 your report?  16 A. Okay.  17 Q. Why don't you just tell me there is no list in  18 your report, and then we can move on to the next  19 question?  20 A. Well, you can --  21 MS. GAYLE: Objection. Argumentative. Motion to  22 strike counsel's preface to the question.  23 BY THE WITNESS:  24 A. You can -- you can read what is in the report.  25 But I, as an expert, cannot include every possible</p>
<p style="text-align: right;">Page 522</p> <p>1 BY THE WITNESS:  2 A. As I've stated several times now, I go through  3 all of those lists of differential diagnoses in my head.  4 That includes every possible thing that can lead to  5 pelvic pain. I am a member of the International Pelvic  6 Pain Society. This is what I do for a living. But I'm  7 not going to go through and list out every possible  8 diagnosis that could lead to it that I have considered.  9 Because then you're talking about going back 25 years of  10 medical education, neurologic issues, pelvic floor, GYN,  11 endometriosis. So I considered those. I did not go out  12 and spell out each one of those separately, though.  13 Q. Okay. So the list is in your head, not in the  14 report?  15 MS. GAYLE: Object to form.  16 BY MS. GEIST:  17 Q. Is that correct?  18 MS. GAYLE: Mischaracterizes testimony.  19 BY THE WITNESS:  20 A. I've stated that over and over, and I'm going  21 to state the same thing again.  22 Q. I know. But, Doctor, here is my point, okay,  23 at the trial in this case, if Mrs. Alonso's case goes to  24 trial, the judge will ask you to say yes or no, is there  25 a list in your report. And all I'm asking you is to --</p>	<p style="text-align: right;">Page 524</p> <p>1 <b>diagnosis that I consider. I considered endometriosis.</b>  2 <b>I found no support for it. I considered interstitial</b>  3 <b>cystitis. I found no support for it. MS, neurologic,</b>  4 <b>spinal cord injuries, cervical injuries, lumbar injury,</b>  5 <b>lumbar disc disease, I considered all of those. I do</b>  6 <b>not then go and put down all of those in a form that you</b>  7 <b>want.</b>  8 Q. Now, you won't answer my question, but let me  9 ask you this. You said a number of times you can't  10 possibly put down and list every possible alternative  11 cause for the problems Mrs. Alonso is complaining of.  12 Did you put in your report even one possible alternative  13 cause for the problems Mrs. Alonso is complaining of?  14 MS. GAYLE: Object to form.  15 BY MS. GEIST:  16 Q. That you considered and ruled out --  17 MS. GAYLE: Object.  18 BY MS. GEIST:  19 Q. -- in reaching your opinions? Did you include  20 even one medical condition or problem?  21 MS. GAYLE: Object to form. Asked and answered.  22 BY THE WITNESS:  23 A. Okay. In my opinion, I considered all  24 potential differential diagnoses. The report states  25 what the report states. I did not go through and list</p>

<p style="text-align: right;">Page 525</p> <p><b>1 out all that I had considered.</b></p> <p>2 Q. You didn't even list one though, correct?</p> <p>3 MS. GAYLE: Objection. Asked and answered, and</p> <p>4 mischaracterizes his testimony.</p> <p>5 BY THE WITNESS:</p> <p><b>6 A. I considered all based upon my experience at a</b></p> <p><b>7 tertiary medical center, a member of the International</b></p> <p><b>8 Pelvic Pain Society, who deals with meshes, pain, et</b></p> <p><b>9 cetera, on a daily basis. I considered all. I did not</b></p> <p><b>10 go through and list out all of the possible</b></p> <p><b>11 contributions that went through my head in coming up</b></p> <p><b>12 with a diagnoses.</b></p> <p>13 Q. All right. In the interest of time, Doctor,</p> <p>14 I'm going to move on. But can you tell me specifically</p> <p>15 for Mrs. Alonso what specific medical conditions or</p> <p>16 problems did you consider for her as a specific</p> <p>17 plaintiff in reaching your differential diagnosis?</p> <p><b>18 A. I considered -- again, the list is large. I</b></p> <p><b>19 considered dealing with central nervous system</b></p> <p><b>20 conditions, Parkinson's, MS, brain trauma, radiation to</b></p> <p><b>21 the brain, spinal cord injuries, cervical, thoracic,</b></p> <p><b>22 lumbar, lumbar disc disease, endometriosis, interstitial</b></p> <p><b>23 cystitis, ovarian etiologies, ovarian remnant, pelvic</b></p> <p><b>24 congestion syndrome, primary bladder dysfunction,</b></p> <p><b>25 neurologic injury, local diabetes, myositis.</b></p>	<p style="text-align: right;">Page 527</p> <p><b>1 diagnoses due to the inflammation of the product within</b></p> <p><b>2 her body. I found no evidence of a central nervous</b></p> <p><b>3 system defect in her.</b></p> <p>4 Q. In reaching your differential diagnosis for</p> <p>5 Mrs. Alonso, did you consider her history with heavy</p> <p>6 bleeding and clots as a possible alternative cause for</p> <p>7 some of the pain and discomfort she's complaining about?</p> <p><b>8 A. Yes and no to that. Yes. She had heavy</b></p> <p><b>9 periods, abnormalities of uterine issues. However, that</b></p> <p><b>10 was prior to her surgery. Following her surgery and no</b></p> <p><b>11 longer having a uterus, those issues are excluded.</b></p> <p>12 Q. Did you consider, in reaching your</p> <p>13 differential diagnosis, the fact that Mrs. Alonso had</p> <p>14 been diagnosed with diverticulitis?</p> <p><b>15 A. Yes. Diverticulitis, colon issues, are</b></p> <p><b>16 considered in a differential diagnosis. However, in</b></p> <p><b>17 dealing with being an expert in pelvic pain and a member</b></p> <p><b>18 of the International Pelvic Pain Society, pelvic pain</b></p> <p><b>19 due to diverticulitis, diverticulosis, or a perforated</b></p> <p><b>20 diverticulum is different than this type of pain.</b></p> <p>21 Q. Diverticulitis, the primary presentation of</p> <p>22 that medical condition is pelvic pain, true?</p> <p><b>23 A. It possibly can be pelvic pain if it ruptures.</b></p> <p><b>24 It is also associated with fever, chills, systemic</b></p> <p><b>25 defects, and usually located on the left-hand side where</b></p>
<p style="text-align: right;">Page 526</p> <p>1 Q. Did you see anything, when you reviewed</p> <p>2 Mrs. Alonso's medical records, anything specific in</p> <p>3 Mrs. Alonso's history that you considered and ruled out</p> <p>4 as a potential cause of her problems in reaching your</p> <p>5 differential diagnosis?</p> <p>6 MS. GAYLE: Objection, form. And objection, asked</p> <p>7 and answered.</p> <p>8 BY THE WITNESS:</p> <p><b>9 A. Yeah. I mean, as far as when I reviewed her</b></p> <p><b>10 medical records, I guess I'm confused on your question.</b></p> <p>11 Q. Yeah. Well, you just gave me a long list of</p> <p>12 things that may or may not apply to Mrs. Alonso. Did</p> <p>13 you -- did you -- when you reviewed her medical history</p> <p>14 and her medical records, was there anything that you</p> <p>15 considered about Mrs. Alonso's history that you ruled</p> <p>16 out in reaching your differential diagnosis that the</p> <p>17 Bard Avaulta product was the cause of her problems?</p> <p>18 MS. GAYLE: Objection.</p> <p><b>19 THE WITNESS: I --</b></p> <p>20 MS. GAYLE: Asked and answered.</p> <p>21 BY THE WITNESS:</p> <p><b>22 A. I ruled out that list I just went off of,</b></p> <p><b>23 however many those were. I ruled those out as the</b></p> <p><b>24 primary cause of her problem. Issues like myositis,</b></p> <p><b>25 inflammation of the muscle, could be one of the</b></p>	<p style="text-align: right;">Page 528</p> <p><b>1 the sigmoid is located.</b></p> <p>2 Q. So did you consider diverticulitis --</p> <p>3 diverticulitis as a possible cause for some of the</p> <p>4 pelvic pain problems Mrs. Alonso is complaining of?</p> <p>5 MS. GAYLE: Objection. Asked and answered.</p> <p>6 BY THE WITNESS:</p> <p><b>7 A. As I mentioned, absolutely, but then I</b></p> <p><b>8 analyzed and I have a fairly extensive -- because I'm a</b></p> <p><b>9 reconstructive surgeon and a member of the International</b></p> <p><b>10 Pelvic Pain Society, diverticulitis, she had no evidence</b></p> <p><b>11 of active diverticulitis. Diverticulosis is not</b></p> <p><b>12 commonly associated with pain. It's also a different</b></p> <p><b>13 type of pain. She had no fever, no chills, no evidence</b></p> <p><b>14 of an intraabdominal pelvic abscess.</b></p> <p>15 Q. How about internal hemorrhoids? Did</p> <p>16 Mrs. Alonso have internal hemorrhoids?</p> <p><b>17 A. I don't recall.</b></p> <p>18 Q. Did you consider internal hemorrhoids as a</p> <p>19 possible alternative cause for pelvic pain?</p> <p><b>20 A. Internal hemorrhoids are usually painless.</b></p> <p><b>21 They may bleed per rectum with bright red blood. They</b></p> <p><b>22 will not cause vaginal pain. So, in my experience, that</b></p> <p><b>23 is theoretically a source of bleeding, but it is not a</b></p> <p><b>24 source of vaginal pain or vaginal abscess following a</b></p> <p><b>25 surgery.</b></p>

<p style="text-align: right;">Page 529</p> <p>1 Q. One of the things you mentioned with respect</p> <p>2 to Mrs. Alonso is urge incontinence?</p> <p>3 <b>A. Correct.</b></p> <p>4 Q. Do you -- is it your opinion that the Bard</p> <p>5 Avaulta product caused her to experience urge</p> <p>6 incontinence?</p> <p>7 <b>A. With, again, a review of the literature and</b></p> <p>8 <b>based upon my experience and where the Avaulta mesh is</b></p> <p>9 <b>placed in the vesicovaginal space and reviewing the</b></p> <p>10 <b>surgeon's records, which is consistent where he placed</b></p> <p>11 <b>it -- those are where the nerves for bladder function</b></p> <p>12 <b>occur -- if a mesh becomes infected or inflamed or</b></p> <p>13 <b>contracts, it will affect those nerves. So, yes, that</b></p> <p>14 <b>could be a source of her overreactive bladder.</b></p> <p>15 Q. Did you consider the fact that she was</p> <p>16 diagnosed with overreactive bladder or urge</p> <p>17 incontinence -- those are the same things, right,</p> <p>18 Doctor? Don't we -- don't medical doctors use those</p> <p>19 terms interchangeably? Urge incontinence means</p> <p>20 overreactive bladder syndrome?</p> <p>21 MS. GAYLE: Object to form.</p> <p>22 BY THE WITNESS:</p> <p>23 <b>A. Overreactive bladder is the entire</b></p> <p>24 <b>constellation of symptoms of urgency, frequency, urge</b></p> <p>25 <b>incontinence, where urge incontinence is a more specific</b></p>	<p style="text-align: right;">Page 531</p> <p>1 syndrome at the end of 2013?</p> <p>2 MS. GAYLE: Objection.</p> <p>3 BY MS. GEIST:</p> <p>4 Q. If she had said that, does that mean that the</p> <p>5 Bard products could not have been increasing the</p> <p>6 severity of the overreactive bladder syndrome?</p> <p>7 MS. GAYLE: Objection. Objection. Form.</p> <p>8 BY THE WITNESS:</p> <p>9 <b>A. Absolutely not. Because, remember, the</b></p> <p>10 <b>vesicovaginal plexus, which are the nerves that control</b></p> <p>11 <b>bladder function, are located in the vesicovaginal plane</b></p> <p>12 <b>where the Avaulta mesh goes. So, if you have a mesh</b></p> <p>13 <b>that contracts, degrades, causes inflammation and traps</b></p> <p>14 <b>nerves, that can lead to progression of the disease just</b></p> <p>15 <b>like we see progression and increase of mesh extrusion.</b></p> <p>16 Q. Are you aware that Mrs. Alonso has a history</p> <p>17 of extensive lumbar disc disease, joint swelling?</p> <p>18 <b>A. Correct.</b></p> <p>19 Q. Back problems?</p> <p>20 <b>A. Correct.</b></p> <p>21 Q. You're aware of all of that?</p> <p>22 <b>A. Well, I would have to go back and look at the</b></p> <p>23 <b>records at exactly where all of the lumbar disc disease</b></p> <p>24 <b>is. But lumbar disc disease is in my differential</b></p> <p>25 <b>diagnosis, as I mentioned earlier, of neurologic</b></p>
<p style="text-align: right;">Page 530</p> <p>1 subset within that.</p> <p>2 Q. Did you consider the fact that she was</p> <p>3 diagnosed with an overreactive bladder and was on</p> <p>4 Vesicare prior to the implant of the Bard product?</p> <p>5 <b>A. Absolutely. And so my previous answer was</b></p> <p>6 <b>that the Avaulta, where it's located, is going to be</b></p> <p>7 <b>contributing to possibly worsening of that condition.</b></p> <p>8 Q. Can you say, with a reasonable degree of</p> <p>9 medical certainty, that the Bard product changed, in any</p> <p>10 way, the condition she already had prior to the implant?</p> <p>11 <b>A. I would have to look at, and I'd have to go</b></p> <p>12 <b>back and look at her records here, the chronologic --</b></p> <p>13 <b>the chronology of the situation, the severity of her</b></p> <p>14 <b>overreactive bladder prior to and after and then</b></p> <p>15 <b>currently.</b></p> <p>16 <b>If the disease process has dramatically</b></p> <p>17 <b>increased following the implantation of it, the Avaulta</b></p> <p>18 <b>may not be the primary cause if she had a preexisting</b></p> <p>19 <b>condition, but it can worsen it. The same thing if an</b></p> <p>20 <b>individual has pelvic pain prior to surgery, but it</b></p> <p>21 <b>increases dramatically. The Avaulta may not have caused</b></p> <p>22 <b>the underlying problem, but then it worsens the</b></p> <p>23 <b>condition.</b></p> <p>24 Q. Did you consider the fact that Mrs. Alonso had</p> <p>25 said she had no complaints of overreactive bladder</p>	<p style="text-align: right;">Page 532</p> <p>1 abnormalities.</p> <p>2 Q. Did you consider those conditions as possibly</p> <p>3 contributing to Mrs. Alonso's complaints of pain?</p> <p>4 MS. GAYLE: Object.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. And lack of physical intimacy?</p> <p>7 MS. GAYLE: Objection. Asked and answered</p> <p>8 previously.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A. Yes. Based upon my education and the fact</b></p> <p>11 <b>that I did a fellowship in what's called neurourology</b></p> <p>12 <b>and a member of the International Pelvic Pain Society,</b></p> <p>13 <b>I'm very well aware and one of the leaders in the field</b></p> <p>14 <b>as far as the understanding of neuroanatomy and its</b></p> <p>15 <b>effects upon the pelvis.</b></p> <p>16 <b>Lumbar disc disease can, no question, cause</b></p> <p>17 <b>pain. But leading to isolated pelvic pain where there</b></p> <p>18 <b>is a firm nodule in the vagina, lumbar disc disease does</b></p> <p>19 <b>not cause that. If you isolate it to causing foot pain,</b></p> <p>20 <b>leg pain, sciatic-type pain, then Avaulta does not cause</b></p> <p>21 <b>that. Disc disease causes that.</b></p> <p>22 Q. Does Mrs. Alonso have a handicapped sticker on</p> <p>23 her car?</p> <p>24 MS. GAYLE: Objection.</p> <p>25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 533</p> <p>1 <b>A. I have no knowledge.</b></p> <p>2 Q. You have no -- I thought you said you read her</p> <p>3 deposition?</p> <p>4 MS. GAYLE: Objection, Counsel. Mischaracterizes</p> <p>5 his testimony.</p> <p>6 BY MS. GEIST:</p> <p>7 Q. Did you read her deposition?</p> <p>8 <b>A. Yes. I read her deposition. I do not</b></p> <p>9 <b>remember every word of her deposition, and I read many</b></p> <p>10 <b>people's depositions of hundreds and hundreds of pages.</b></p> <p>11 <b>I cannot recall every single word of it.</b></p> <p>12 Q. Did you -- so you have no idea why she has</p> <p>13 that handicapped sticker on her car --</p> <p>14 MS. GAYLE: Objection.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. -- what medical condition caused her to get</p> <p>17 that handicapped sticker?</p> <p>18 MS. GAYLE: Objection, Counsel.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. I've already answered the question. If I</b></p> <p>21 <b>didn't know she had a handicapped sticker, I don't know</b></p> <p>22 <b>why she would have a handicapped sticker.</b></p> <p>23 Q. Did you read in her deposition how she</p> <p>24 testified that it's hard for her to walk and she has</p> <p>25 pain when she walks and that's the reason why she has</p>	<p style="text-align: right;">Page 535</p> <p>1 <b>know what was in the deposition. I've asked to see this</b></p> <p>2 <b>deposition, to look at that in its entirety. Not that I</b></p> <p>3 <b>don't doubt you, but I would like to see the whole</b></p> <p>4 <b>comment.</b></p> <p>5 Q. So you don't know the medical condition that</p> <p>6 caused her to go and get the sticker?</p> <p>7 MS. GAYLE: Objection.</p> <p>8 BY MS. GEIST:</p> <p>9 Q. Is that -- is that true?</p> <p>10 MS. GAYLE: Objection to form. Objection, asked</p> <p>11 and answered. Objection, mischaracterizes Mrs. Alonso's</p> <p>12 testimony.</p> <p>13 BY THE WITNESS:</p> <p>14 <b>A. I think the best thing, let's take a look at</b></p> <p>15 <b>that deposition and what she states. I would like to</b></p> <p>16 <b>see, in the entirety, those comments.</b></p> <p>17 Q. So the answer to my question is, you don't</p> <p>18 know the medical condition for which she got a</p> <p>19 handicapped sticker on her car?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. And which causes her pain with walking?</p> <p>23 MS. GAYLE: Objection.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Is that true, Doctor?</p>
<p style="text-align: right;">Page 534</p> <p>1 the handicapped sticker due to a specific medical</p> <p>2 condition?</p> <p>3 MS. GAYLE: Object to form.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. Okay. I would like -- the important thing,</b></p> <p>6 <b>probably, let's pull out that deposition and read that</b></p> <p>7 <b>exactly because I would like to know what type of pain</b></p> <p>8 <b>she is describing. In my interaction with her, as I've</b></p> <p>9 <b>talked about it here, neurologic issues related to</b></p> <p>10 <b>lumbar disc disease can cause pain in the legs, can</b></p> <p>11 <b>cause difficulty ambulating. No question it can do it.</b></p> <p>12 <b>But when I'm also then correlating that with</b></p> <p>13 <b>my exam and my interaction with her as far as what pain</b></p> <p>14 <b>happens when standing, sitting, lying down and then the</b></p> <p>15 <b>physical exam. As I mentioned, lumbar disc disease will</b></p> <p>16 <b>not cause pinpoint tenderness in the obturator foramen</b></p> <p>17 <b>and will not cause scarring in the vagina.</b></p> <p>18 Q. Sitting here today, do you know why, what</p> <p>19 specific medical condition Mrs. Alonso has that caused</p> <p>20 her to go and get a handicapped sticker for her car?</p> <p>21 MS. GAYLE: Object to form. Asked and answered.</p> <p>22 BY THE WITNESS:</p> <p>23 <b>A. I've already stated I did not know she had a</b></p> <p>24 <b>handicapped sticker. The fact that she does tells me</b></p> <p>25 <b>that she's got some impairment. I do not -- I don't</b></p>	<p style="text-align: right;">Page 536</p> <p>1 MS. GAYLE: Objection. Asked and answered.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. You are asking me to trust what you are</b></p> <p>4 <b>stating. And I would like to see that document and</b></p> <p>5 <b>let's look through it. I will be more than happy to</b></p> <p>6 <b>render an opinion based upon that deposition.</b></p> <p>7 Q. Did -- after a woman has a pelvic floor</p> <p>8 surgery like the type Mrs. Alonso had, the implant of a</p> <p>9 transvaginal mesh product to repair a pelvic organ</p> <p>10 prolapse, after a woman has such a procedure, are they</p> <p>11 normally instructed by a physician to not engage in</p> <p>12 sexual intercourse for a specific period of time?</p> <p>13 <b>A. I can't speak to what happens in every</b></p> <p>14 <b>practice. I know what my instructions are.</b></p> <p>15 Q. What are your -- what are you instructions?</p> <p>16 <b>A. No sexual activity for six weeks.</b></p> <p>17 Q. Why?</p> <p>18 <b>A. For concerns about breaking down the incision.</b></p> <p>19 Q. So if a woman engages in sexual intercourse</p> <p>20 during that six-week healing process, what could happen</p> <p>21 to the incision?</p> <p>22 <b>A. Well, since I don't use any meshes, it will</b></p> <p>23 <b>just probably delay healing a bit because the incision</b></p> <p>24 <b>could break down. It's much more of an important issue</b></p> <p>25 <b>when meshes are in place.</b></p>



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<p style="text-align: right;">Page 537</p> <p>1 Q. Is that because it could actually cause some 2 sort of mesh exposure and open the -- open the incision, 3 in other words? 4 <b>A. Possible --</b> 5 MS. GAYLE: Object to form. 6 BY THE WITNESS: 7 <b>A. Possibly. I am unaware of any. I would have</b> 8 <b>to look at the IFU, what Bard warns as far as how long</b> 9 <b>to avoid sexual activity.</b> 10 Q. Would you agree with me, if a woman engages in 11 sexual activity before being cleared by her doctor, that 12 that would not be a good thing and could possibly cause 13 complications? 14 <b>A. I disagree with that.</b> 15 Q. I thought you just told me that, if a woman 16 engages in sexual intercourse during the healing 17 process, that could cause some complications with 18 respect to healing and the suture? 19 <b>A. That -- I answered that. That's correct.</b> 20 Q. Okay. 21 <b>A. But your other question was different.</b> 22 Q. Did you consider, in reaching your opinions 23 with respect to Mrs. Alonso and the complications she 24 had that you say resulted from the Bard Avaulta product, 25 did you consider the fact that she may have engaged in</p>	<p style="text-align: right;">Page 539</p> <p>1 <b>records to see when she regained. There is going to be</b> 2 <b>a lot of qualifiers. Did she resume sexual activity two</b> 3 <b>days postop or four weeks, six weeks, eight weeks?</b> 4 Q. Do you know, from your review of the records 5 in Mrs. Alonso's case, when she began resuming sexual 6 activity and whether she, in fact, adhered to her 7 doctor's instructions; do you know that? 8 MS. GAYLE: Object to form. 9 BY THE WITNESS: 10 <b>A. I would want to see the records. I don't</b> 11 <b>recall.</b> 12 Q. You do not recall sitting here today? 13 <b>A. I do not recall the specifics of that. That's</b> 14 <b>why I'd want to see the records, to refresh my memory.</b> 15 Q. Doctor, you talk in your report about the lack 16 of physical intimacy has already cost Mrs. Alonso a 17 major component to her quality of life. And then you 18 state long-term impact on her quality of life is 19 difficult to accurately ascertain, however many studies 20 have shown long-term negative impact leads to feelings 21 of isolation, loneliness, depression, and suicide. Did 22 I read that correctly? 23 <b>A. Correct.</b> 24 Q. And that is actually an identical opinion that 25 you provided in Mrs. Wheeler's and Mrs. Bolyard's case,</p>
<p style="text-align: right;">Page 538</p> <p>1 sexual intercourse prior to being cleared by her doctor? 2 MS. GAYLE: Objection to form. Objection, 3 mischaracterizes the testimony of the parties. 4 BY THE WITNESS: 5 <b>A. I don't know what she was instructed. We</b> 6 <b>would have to go look back at the medical records of</b> 7 <b>what she was instructed. Clearance by a medical doctor</b> 8 <b>does not necessarily have to be done if there is an</b> 9 <b>appropriate amount of waiting.</b> 10 <b>So, again, we would have to look at the</b> 11 <b>records and see what she was instructed and when sexual</b> 12 <b>activity began. And we'd also have to look at the</b> 13 <b>medical literature to determine are there any studies</b> 14 <b>out there showing when it is appropriate to regain</b> 15 <b>sexual activity.</b> 16 Q. And certainly, Doctor, you would agree with me 17 that, if a woman engages in sexual activity too soon 18 after a vaginal surgery, complications could occur? 19 MS. GAYLE: Objection. Form. 20 BY THE WITNESS: 21 <b>A. There's -- there's too many variables there.</b> 22 <b>It depends upon the time of it, the health of the woman,</b> 23 <b>steroid status. Multiple factors come into play.</b> 24 Q. Is it a possibility? 25 <b>A. Again, I would have to look at the medical</b></p>	<p style="text-align: right;">Page 540</p> <p>1 true? 2 <b>A. That is correct, with medical literature to</b> 3 <b>support that.</b> 4 Q. Are you saying here, Doctor, that Mrs. Alonso 5 will necessarily experience depression and kill herself 6 because of the issues that she's complaining of in this 7 litigation? 8 MS. GAYLE: Objection to form. Mischaracterizes 9 his opinions. 10 BY THE WITNESS: 11 <b>A. In dealing with patients on a day-to-day</b> 12 <b>basis, review of the literature, being a member of the</b> 13 <b>International Pelvic Pain Society, one of the elite</b> 14 <b>societies on pelvic pain, isolation, depression due to</b> 15 <b>lack of physical intimacy, a guilt sensation to this can</b> 16 <b>possibly lead to depression, isolation, and suicide, as</b> 17 <b>I mentioned.</b> 18 Q. Did -- did you consider any other problems in 19 Mrs. Alonso's life that could contribute to the cause -- 20 I'm sorry -- that could contribute to quality-of-life 21 issues, depression, issues relating to these things 22 you've raised in your report? 23 <b>A. Yes. Yes, I did.</b> 24 Q. So did you consider her other problems such as 25 the husband being in jail who was cheating on her? Did</p>

<p style="text-align: right;">Page 541</p> <p>1 you consider those things?</p> <p>2 MS. GAYLE: Objection, form.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. Oh, well, by all means. A husband being in</b></p> <p>5 <b>jail and those types of issues will definitely add</b></p> <p>6 <b>stress to her life. Compounded by the fact that she has</b></p> <p>7 <b>pelvic pain, that is a major issue. A husband that is</b></p> <p>8 <b>in jail will not cause extreme vaginal pain on my exam.</b></p> <p>9 Q. But you would -- do you know how long her</p> <p>10 husband was in jail?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY MS. GEIST:</p> <p>13 Q. Do you know how long the couple was separated</p> <p>14 because her husband was incarcerated?</p> <p>15 MS. GAYLE: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 <b>A. No. How long?</b></p> <p>18 Q. You don't know?</p> <p>19 <b>A. I just said I don't know.</b></p> <p>20 Q. Okay. Well, I thought you said you read her</p> <p>21 deposition.</p> <p>22 MS. GAYLE: Objection, Counsel. Mischaracterizes</p> <p>23 his testimony. He's reviewed thousands of pages.</p> <p>24 BY THE WITNESS:</p> <p>25 <b>A. I am under the understanding a deposition like</b></p>	<p style="text-align: right;">Page 543</p> <p>1 <b>sometimes divorce actually improves quality of life.</b></p> <p>2 Q. So I don't think that answered my question,</p> <p>3 though.</p> <p>4 <b>A. It absolutely answered it.</b></p> <p>5 Q. Could the -- could the personal problems that</p> <p>6 Mrs. Alonso has experienced in her marriage, including a</p> <p>7 husband who is incarcerated for years who has cheated on</p> <p>8 her, who has left her, could these issues have caused</p> <p>9 her quality of life issues and depression issues</p> <p>10 separate and apart from issues she says she has from the</p> <p>11 Bard Avaulta product? Could she have any of those</p> <p>12 issues if she never even had the Bard Avaulta product</p> <p>13 implanted?</p> <p>14 <b>A. I keep an open mind about this. That's why I</b></p> <p>15 <b>mentioned, women undergoing stress of a husband who is</b></p> <p>16 <b>cheating, who is incarcerated, and he is taken out of</b></p> <p>17 <b>her life could improve quality of life.</b></p> <p>18 Q. But could also result in a decline of quality</p> <p>19 of life? You're not going to disagree with me on that,</p> <p>20 are you, Doctor?</p> <p>21 MS. GAYLE: Object to form. Argumentative.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. You don't -- you don't think a woman can</p> <p>24 experience depression and a decrease in quality of life</p> <p>25 when she has a husband who is cheating on her and is</p>
<p style="text-align: right;">Page 542</p> <p>1 <b>this is not a memory test. So I've asked you let's see</b></p> <p>2 <b>the deposition and let's go over it. If it's in there,</b></p> <p>3 <b>I'm very open and let's consider it. But no matter,</b></p> <p>4 <b>let's say he's been in prison 30 years, that will not</b></p> <p>5 <b>cause vaginal pain on my exam.</b></p> <p>6 Q. No. But a husband with an extended history of</p> <p>7 incarceration could certainly cause a woman depression</p> <p>8 and quality-of-life issues? Would you agree with me on</p> <p>9 that?</p> <p>10 MS. GAYLE: Objection. Are you talking about</p> <p>11 generally for a random person, or are you talking about</p> <p>12 in a specific case?</p> <p>13 BY MS. GEIST:</p> <p>14 Q. No. I'm talking about Ms. Alonso. If</p> <p>15 Mrs. Alonso was in a marriage where her husband was</p> <p>16 incarcerated for five years, where she actually filed</p> <p>17 for divorce, where he actually moved out, and she</p> <p>18 testified he was cheating on her multiple times in the</p> <p>19 marriage, could all of these things cause her to</p> <p>20 experience quality-of-life issues such as depression?</p> <p>21 MS. GAYLE: Objection. Mischaracterizes</p> <p>22 Mrs. Alonso's testimony and her husband's testimony.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. In day-to-day interaction with women in my</b></p> <p>25 <b>clinic, day-to-day interaction with women in the public,</b></p>	<p style="text-align: right;">Page 544</p> <p>1 tossed in jail for drug-related issues?</p> <p>2 MS. GAYLE: Objection. Form and mischaracterizes</p> <p>3 testimony.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. I could see a large number of women being</b></p> <p>6 <b>actually thrilled to get rid of a man in their life.</b></p> <p>7 Q. Could you also see a large number of women</p> <p>8 experiencing depression after a husband cheats on them?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A. That would be a possibly devastating part of</b></p> <p>12 <b>her life, and that's why she might be happy if he goes</b></p> <p>13 <b>off to prison.</b></p> <p>14 Q. Do you -- do you know the status of</p> <p>15 Mrs. Alonso's marriage at this point in time? Do you</p> <p>16 know whether she took him back or not?</p> <p>17 MS. GAYLE: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A. I don't recall.</b></p> <p>20 Q. If she took him back into the marital home</p> <p>21 right before her deposition, would that change your</p> <p>22 opinion on whether or not she was negatively impacted</p> <p>23 when he was gone in jail for five years?</p> <p>24 MS. GAYLE: Objection. Form. Objection.</p> <p>25 Mischaracterizes his testimony.</p>

<p style="text-align: right;">Page 545</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A. I could see that being a wonderful source of</b></p> <p>3 <b>joy, that they've reconciled themselves, and now they're</b></p> <p>4 <b>left with a painful vagina and they cannot engage in</b></p> <p>5 <b>intercourse and intimacy.</b></p> <p>6 Q. The dyspareunia is one of these things you</p> <p>7 note with respect to Mrs. Alonso, and you attribute that</p> <p>8 as well to the Bard Avaulta product, correct?</p> <p>9 <b>A. Yes. As we mentioned earlier, the Align</b></p> <p>10 <b>product also goes to the exact same location as the</b></p> <p>11 <b>Avaulta product. It is my opinion, based upon my</b></p> <p>12 <b>experience, review of the literature and exam, that</b></p> <p>13 <b>statistically speaking with medical certainty it's going</b></p> <p>14 <b>to be the Avaulta product.</b></p> <p>15 Q. Would you agree with me, Doctor, that</p> <p>16 dyspareunia is what we call sort of a nonspecific</p> <p>17 complaint?</p> <p>18 MS. GAYLE: Object to form.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. I think it's very, very specific.</b></p> <p>21 Q. Are there --</p> <p>22 <b>A. It's painful with sex -- sexual -- it is pain</b></p> <p>23 <b>with sexual activity, so that's very specific.</b></p> <p>24 Q. Are there a number of physical and</p> <p>25 psychological reasons that a woman may experience</p>	<p style="text-align: right;">Page 547</p> <p>1 <b>A. Psychological reasons can be one of the</b></p> <p>2 <b>considerations. However, women with stressors will not</b></p> <p>3 <b>have pinpoint obturator foramen tenderness and scarring</b></p> <p>4 <b>of the vagina.</b></p> <p>5 Q. Mrs. Alonso has certain stressors like what I</p> <p>6 indicated to you earlier relating to a cheating husband,</p> <p>7 a husband who is incarcerated. Could those contribute</p> <p>8 and cause dyspareunia?</p> <p>9 <b>A. They will not cause a scarred vagina and</b></p> <p>10 <b>pinpoint tenderness of the obturator foramen.</b></p> <p>11 Q. That wasn't my question, though. Could those</p> <p>12 things cause dyspareunia? If a woman has a husband</p> <p>13 who's cheated on her, and she knows it, the woman has</p> <p>14 stress in her marriage because the husband is</p> <p>15 incarcerated for a number of years, could those things</p> <p>16 have a psychological impact on that woman and cause her</p> <p>17 to experience dyspareunia?</p> <p>18 MS. GAYLE: Objection. Asked and answered.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. If the husband is her sole sexual partner and</b></p> <p>21 <b>he's in prison and not having sexual activity, they</b></p> <p>22 <b>won't have dyspareunia.</b></p> <p>23 Q. I don't think you answered my question,</p> <p>24 Doctor. Can you answer my question? And my question</p> <p>25 was, could those facts, as I laid them out to you, cause</p>
<p style="text-align: right;">Page 546</p> <p>1 dyspareunia?</p> <p>2 MS. GAYLE: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. There are multiple different things that have</b></p> <p>5 <b>to be and should be considered when evaluating a woman</b></p> <p>6 <b>for dyspareunia.</b></p> <p>7 Q. Many, many women experience dyspareunia who</p> <p>8 have not had a transvaginal mesh implanted. Would you</p> <p>9 agree with me on that?</p> <p>10 MS. GAYLE: Object to form.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. But then we would have to look at the</b></p> <p>13 <b>severity, the location, the physical exam, the</b></p> <p>14 <b>chronology of that.</b></p> <p>15 Q. Have you considered other causes for</p> <p>16 Mrs. Alonso's complaints of dyspareunia?</p> <p>17 <b>A. Absolutely. Every patient I see, on a</b></p> <p>18 <b>day-to-day basis, I keep an open mind to the</b></p> <p>19 <b>differential diagnosis of what caused it. That's why we</b></p> <p>20 <b>have to look at the chronology, what surgeries were</b></p> <p>21 <b>done, familial factors, et cetera.</b></p> <p>22 Q. I've seen in the literature and at least on</p> <p>23 the Mayo Clinic site that dyspareunia can be caused in a</p> <p>24 woman for psychological reasons. Would you agree with</p> <p>25 that?</p>	<p style="text-align: right;">Page 548</p> <p>1 a woman to experience dyspareunia?</p> <p>2 MS. GAYLE: Objection. Asked and answered three</p> <p>3 times now.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. The definition of dyspareunia is pain during</b></p> <p>6 <b>sexual activity. If the woman is not having sexual</b></p> <p>7 <b>activity, there will not be pain during sexual activity</b></p> <p>8 <b>because it does not exist. So the husband being</b></p> <p>9 <b>incarcerated, gone from the family, will not cause</b></p> <p>10 <b>dyspareunia. Dyspareunia -- dyspareunia can only be</b></p> <p>11 <b>during sexual activity. Pain during a physical exam,</b></p> <p>12 <b>pinpoint tenderness, scarring of the vagina exists</b></p> <p>13 <b>regardless of the husband's status.</b></p> <p>14 Q. So I still think you're not answering my</p> <p>15 question. So let me try it a different way. Let's</p> <p>16 assume the husband is free from jail, he's back in the</p> <p>17 marital home right before the deposition, conveniently,</p> <p>18 and the couple is engaging in sexual intercourse. Could</p> <p>19 that history with that husband cheating, the other</p> <p>20 stressors in the marriage, could that cause a woman such</p> <p>21 as Mrs. Alonso to experience dyspareunia?</p> <p>22 MS. GAYLE: Objection. Asked and answered four</p> <p>23 times now.</p> <p>24 BY THE WITNESS:</p> <p>25 <b>A. Yeah. We keep going around and around with</b></p>



<p style="text-align: right;">Page 549</p> <p>1 <b>this.</b></p> <p>2 Q. Well, we are, Doctor, because, you know, with</p> <p>3 all due respect, you're not answering my question.</p> <p>4 You're avoiding it like I've never seen.</p> <p>5 <b>A. With all due respect, I am answering it very,</b></p> <p>6 <b>very well based upon my experience as a surgeon in a</b></p> <p>7 <b>tertiary care center who takes care of these patients on</b></p> <p>8 <b>a day-to-day basis. A husband who comes back -- and I</b></p> <p>9 <b>take offense to the conveniently comes back. That is a</b></p> <p>10 <b>pretty negative comment to put on the record for this</b></p> <p>11 <b>poor woman who is suffering, who I examined. I'm the</b></p> <p>12 <b>only person in this room who has examined this woman.</b></p> <p>13 <b>I'm the only person who's talked to her and felt in the</b></p> <p>14 <b>vagina as far as where this pain is. And, again, maybe</b></p> <p>15 <b>they've reconciled and her life is good and she's happy,</b></p> <p>16 <b>and now she cannot become sexually active and intimate</b></p> <p>17 <b>and loses that segment of her life.</b></p> <p>18 Q. You don't -- you don't consider the</p> <p>19 possibility that Mr. -- that Mrs. Alonso's husband moved</p> <p>20 back in with her two weeks before the deposition for the</p> <p>21 purpose of the lawsuit and what they're pursuing in the</p> <p>22 lawsuit? You don't consider that as a possibility?</p> <p>23 MS. GAYLE: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 <b>A. Number one, I am a surgeon here concerning her</b></p>	<p style="text-align: right;">Page 551</p> <p>1 <b>A. Yeah. I would have to look at those exactly,</b></p> <p>2 <b>but I would not doubt they'd be similar.</b></p> <p>3 Q. Okay. Well, they're actually exact. We can</p> <p>4 put them side by side if you want. But it's your</p> <p>5 opinion, in each of these three cases, that the pelvic</p> <p>6 pain and dyspareunia are highly unlikely to be resolved</p> <p>7 and that these women will have these conditions for the</p> <p>8 rest of their lives, correct?</p> <p>9 <b>A. Yeah. In my experience at a tertiary medical</b></p> <p>10 <b>center, a member of the International Pain Society --</b></p> <p>11 <b>Pelvic Pain Society with women who have come which I see</b></p> <p>12 <b>on a daily basis, I have yet to see one recover normal</b></p> <p>13 <b>sexual functions.</b></p> <p>14 Q. Well, you're not a pelvic pain specialist or a</p> <p>15 pain specialist; is that correct?</p> <p>16 MS. GAYLE: Object to form.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A. Absolutely, I'm a pelvic pain specialist.</b></p> <p>19 Q. You are?</p> <p>20 <b>A. This is what I do on a daily basis, yes.</b></p> <p>21 <b>That's what female pelvic medicine and reconstructive</b></p> <p>22 <b>subspecialty approved by the boards of urogyn and</b></p> <p>23 <b>urology do.</b></p> <p>24 Q. Aren't there doctors who hold themselves out</p> <p>25 as pain specialists in the medical community?</p>
<p style="text-align: right;">Page 550</p> <p>1 <b>medical condition. The motivations behind those</b></p> <p>2 <b>individuals you'll have to ask them. That would be best</b></p> <p>3 <b>to have them answer that question.</b></p> <p>4 Q. You have some opinions in your report, Doctor,</p> <p>5 that we talked about a little bit already with respect</p> <p>6 to long-term outcome and prognosis. Do you see that in</p> <p>7 your report?</p> <p>8 <b>A. Correct.</b></p> <p>9 Q. And your opinions, as I understand them, is</p> <p>10 that for both Mrs. Alonso's reported pelvic pain and</p> <p>11 dyspareunia, you say the prognosis is poor, and it is</p> <p>12 highly unlikely that Mrs. Alonso will have a complete</p> <p>13 resolution of her pelvic pain and her sexual</p> <p>14 dysfunction. Is that -- are those your opinions,</p> <p>15 Doctor?</p> <p>16 <b>A. Correct. In my experience at a major tertiary</b></p> <p>17 <b>center, with highly subspecialized training, dealing</b></p> <p>18 <b>with the scarred -- the vaginal scarring that takes</b></p> <p>19 <b>place following mesh implantation, I have yet to see one</b></p> <p>20 <b>woman with this severe -- with this severe of a reaction</b></p> <p>21 <b>ever regaining normal sexual function.</b></p> <p>22 Q. The -- and you have the same identical opinion</p> <p>23 for Mrs. Wheeler and Mrs. Bolyard as well, correct?</p> <p>24 It's word for word in each of your three reports, this</p> <p>25 section?</p>	<p style="text-align: right;">Page 552</p> <p>1 MS. GAYLE: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. There are anesthesiologists, usually</b></p> <p>4 <b>anesthesiologists, who are pain specialists, but they're</b></p> <p>5 <b>also urologists.</b></p> <p>6 Q. No. I mean doctors who actually treat people</p> <p>7 experiencing chronic pain conditions, like fibromyalgia</p> <p>8 and things of that nature? Aren't there doctors who are</p> <p>9 considered to be pain specialists who hold themselves</p> <p>10 out as pain specialists in the medical community?</p> <p>11 <b>A. Yes, and I'm one of them.</b></p> <p>12 Q. You are?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. You hold yourself out as a pain specialist in</p> <p>15 the medical community?</p> <p>16 <b>A. Absolutely.</b></p> <p>17 Q. Do you treat any other type of pain condition</p> <p>18 other than pelvic pain?</p> <p>19 <b>A. I treat only pelvic pain.</b></p> <p>20 Q. Do you have any particularized education,</p> <p>21 training, or background or advanced degree in the</p> <p>22 treatment of pain generally?</p> <p>23 <b>A. Yes. Yes, I do. And doing a fellowship in</b></p> <p>24 <b>neurourology, okay, which is pelvic neuroanatomy.</b></p> <p>25 <b>That's a one-year advanced training taking and passing</b></p>

<p style="text-align: right;">Page 553</p> <p>1 the credentialing for female pelvic medicine and  2 reconstruction, which is dealing with pelvic pain, being  3 a member of the International Pelvic Pain Society,  4 reviewing literature, attending meetings, yeah, I have  5 an advanced level of understanding of this far more than  6 the average.  7 Q. So you don't refer your patients out -- your  8 patients out to a pain management specialist doctor, for  9 example?  10 A. At times I will, dependent upon my evaluation.  11 If I do not feel there is anything I can do surgically  12 for this woman, then I will -- it's a multispecialty  13 approach. I at times will get my urogynecology  14 colleagues involved. I will get colorectal involved. I  15 may get -- sometimes if they're going to do injections  16 into the spine. I don't do that. I'll get multiple  17 people involved because this is a multispecialty  18 approach to dealing with this problem.  19 Q. You don't perform trigger-point injections or  20 anything of that nature to address complaints of pain;  21 is that true?  22 A. No. I deal more with the surgical management  23 of the pelvic pain, medication management of the pelvic  24 pain. When it comes time to do injections, I have other  25 subspecialists who I feel can treat these individuals</p>	<p style="text-align: right;">Page 555</p> <p>1 therapists within my department. I also have physical  2 medicine, rehab physical therapists that I deal with.  3 Q. Did -- when you met with Mrs. Alonso, did you  4 refer her to a physical therapist or a pain management  5 specialist?  6 A. I make no -- I was very clear with them. I am  7 here to evaluate you. I made no medical  8 recommendations. I gave her no diagnosis. I told her  9 upfront, I am here to evaluate you to come up with an  10 opinion on my own, but I did not talk to her about  11 diagnosis, prognosis, or treatment options.  12 Q. And, by the way, Doctor, can we agree that all  13 of these questions and answers you're providing me on  14 this issue of permanency of the pelvic pain and  15 dyspareunia, that they would also apply -- your same  16 responses would apply to Mrs. Wheeler and Mrs. Bolyard's  17 cases?  18 A. Yeah. I agree completely unless there is some  19 other nuance that pops up.  20 Q. Understood.  21 A. But you're right.  22 Q. Understood. Do you know whether Mrs. Alonso  23 has sought the assistance from a pain management  24 specialist?  25 A. I would have to go back and look at the</p>
<p style="text-align: right;">Page 554</p> <p>1 and have a better chance of it.  2 Q. So a pain management specialist would be a  3 doctor you would refer your patients to if they're going  4 to look into the option of trigger-point injections, for  5 example, to manage pain?  6 MS. GAYLE: Objection. Asked and answered.  7 BY THE WITNESS:  8 A. I need for you to define trigger-point  9 injections then.  10 Q. You don't know what I mean when I use that  11 term?  12 MS. GAYLE: Objection. Mischaracterizes his  13 testimony.  14 BY THE WITNESS:  15 A. Trigger points -- there are trigger points in  16 the spine. There's trigger points in the neck. There's  17 migraine trigger points. So you have to define what  18 you're talking about. I will not do a trigger-point  19 injection for migraines.  20 Q. In reaching your diagnosis, your opinions  21 about the long-term prognosis for Mrs. Alonso, did you  22 consider the availability of physical therapy for the  23 pain?  24 A. Absolutely. That is one of the other  25 individuals in my armamentarium. I have physical</p>	<p style="text-align: right;">Page 556</p> <p>1 records. Off the top of my head, I do not recall.  2 Q. How about Mrs. Wheeler and Mrs. Bolyard? Do  3 you know whether they have sought care and treatment  4 from a pain specialist, pain management specialist,  5 pardon me?  6 A. It's the same answer for all of those.  7 Q. You don't know whether any of those plaintiffs  8 are seeing a pain management doctor?  9 A. I don't recall.  10 Q. In Mrs. Alonso's case, did you consider, in  11 reaching your differential diagnosis, whether there were  12 any -- strike that.  13 In Mrs. Alonso's case, did you consider, in  14 reaching your differential diagnosis, the surgical  15 technique of the implanting doctor, Dr. Suarez?  16 A. Absolutely.  17 Q. The Avaulta -- the Bard Avaulta mesh is  18 supposed to be implanted tension-free. Do you  19 understand that?  20 A. Correct.  21 Q. And that's set forth in the IFU for the  22 product? Can we agree on that?  23 A. I would have to look because I'd have to  24 refresh my memory on the IFU; however, it is well-known  25 and established that it should be placed tension-free.</p>

In Re: CR Bard 200

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<p style="text-align: right;">Page 557</p> <p>1 Q. Okay.</p> <p>2 <b>A. But the definition of tension-free is unknown.</b></p> <p>3 Q. Understood. But that's not something that you</p> <p>4 think would be unknown to an implanting doctor. It's</p> <p>5 well-established the mesh needs to be implanted</p> <p>6 tension-free, and that's in order to allow for the</p> <p>7 tissue ingrowth that is expected with the products; is</p> <p>8 that true?</p> <p>9 <b>A. No. It depends upon when the implantation</b></p> <p>10 <b>took place. In the early years, when there was no</b></p> <p>11 <b>experience with meshes, no one knew what the right</b></p> <p>12 <b>amount of tension would be.</b></p> <p>13 Q. How about --</p> <p>14 <b>A. In --</b></p> <p>15 Q. I'm sorry. Go ahead.</p> <p>16 <b>A. In 2014 -- well, it's not available. Let's</b></p> <p>17 <b>say when it was last available on the market, it would</b></p> <p>18 <b>be a more -- there is a lot more data out there on what</b></p> <p>19 <b>tension-free would be. Now, the reason for tension-free</b></p> <p>20 <b>is because of contraction of the mesh to account for it.</b></p> <p>21 Q. There is a certain degree of contraction due</p> <p>22 to the normal wound healing process after a transvaginal</p> <p>23 mesh is implanted. Is that correct?</p> <p>24 <b>A. Yes. If we looked at various different data,</b></p> <p>25 <b>Letourzney was the one that comes to mind,</b></p>	<p style="text-align: right;">Page 559</p> <p>1 <b>A. Again, I would have to see that note because</b></p> <p>2 <b>I'd have to look at the note in its entirety.</b></p> <p>3 Q. Understood. But as -- and I'm asking you to</p> <p>4 assume what is true as I've just stated to you, and then</p> <p>5 we'll look at the note. But if the note describes that</p> <p>6 the mesh was put in under tension and without proper</p> <p>7 tacking to prevent migration and curling, would that be</p> <p>8 proper surgical technique?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A. I would like to look at that note and then</b></p> <p>12 <b>I'll decide whether I agree with you or not.</b></p> <p>13 MS. GAYLE: Let's take a quick bathroom break,</p> <p>14 Counsel, if you don't mind.</p> <p>15 MS. GEIST: Yeah. Let's take a quick break.</p> <p>16 That's a good idea.</p> <p>17 VIDEO TECHNICIAN: We're off the record. The time</p> <p>18 is 10:39 a.m.</p> <p>19 (A recess was had.)</p> <p>20 VIDEO TECHNICIAN: We're back on the record. The</p> <p>21 time is 10:55 a.m.</p> <p>22 (Elliott Deposition Exhibit Nos. 30 &amp;</p> <p>23 31 were marked for identification.)</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Dr. Elliott, let me hand you what I've marked</p>
<p style="text-align: right;">Page 558</p> <p>1 <b>L-E-T-O-U-R-Z-N-E-Y, et al., after six months, up to 80</b></p> <p>2 <b>percent contraction.</b></p> <p>3 Q. Now, Dr. Suarez implanted Mrs. Alonso's</p> <p>4 Avaulta product on July 19, 2010. Do you understand</p> <p>5 that?</p> <p>6 <b>A. July 19th, 2010, I agree.</b></p> <p>7 Q. Okay. So, at that point in time, was it</p> <p>8 well-known in the medical community that the</p> <p>9 transvaginal mesh product needed to be implanted</p> <p>10 tension-free in your opinion?</p> <p>11 <b>A. I can't say as far as that date. That's in</b></p> <p>12 <b>the middle years of this, so I can't say.</b></p> <p>13 Q. Do you know if the IFU at the time instructed</p> <p>14 the implanting doctor to implant the mesh tension-free?</p> <p>15 <b>A. I would have to look at that IFU and then also</b></p> <p>16 <b>have to know what IFU Dr. Suarez was looking at, too.</b></p> <p>17 Q. Did you look at the operative note from</p> <p>18 Dr. Suarez's surgery?</p> <p>19 <b>A. Yes. I reviewed it closely. I don't recall</b></p> <p>20 <b>it right now. I would like to see it. That would be</b></p> <p>21 <b>helpful.</b></p> <p>22 Q. If the operative note describes that the mesh</p> <p>23 was put in under tension without proper tacking to</p> <p>24 prevent migration and curling, would that have been</p> <p>25 proper surgical technique?</p>	<p style="text-align: right;">Page 560</p> <p>1 during a break as Exhibit 30 and 31 to your deposition.</p> <p>2 And, for the record, Exhibit 30 is the Avaulta Plus</p> <p>3 Biosynthetic Support System IFU dated at the bottom</p> <p>4 October of 2009. And Exhibit 31 is the operative report</p> <p>5 by Dr. Suarez for Mrs. Alonso for the surgical procedure</p> <p>6 performed on July 19th, 2010.</p> <p>7 Let me hand those to you and give a copy to</p> <p>8 your counsel. This is 30 and this is 31.</p> <p>9 MS. GAYLE: Thank you.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. Doctor, directing your attention to Exhibit</p> <p>12 30, which is the IFU for the Avaulta Plus Biosynthetic</p> <p>13 Support System?</p> <p>14 <b>A. Yes.</b></p> <p>15 Q. You've reviewed this before the deposition,</p> <p>16 correct?</p> <p>17 <b>A. Yes, I have.</b></p> <p>18 Q. Okay. And if you go with me to the fourth</p> <p>19 page of the document --</p> <p>20 <b>A. I'm there.</b></p> <p>21 Q. -- under Description, on the second paragraph,</p> <p>22 it states, The monofilament polypropylene mesh used in</p> <p>23 the Avaulta Plus Biosynthetic Support System has a soft</p> <p>24 knit in the central section for compliant organ support</p> <p>25 and host tissue ingrowth, and a strong knit in the</p>

<p style="text-align: right;">Page 561</p> <p>1 lateral sides to provide improved strength for 2 tension-free fixation of the mesh. Do you see that? 3 <b>A. Oh, here we go.</b> 4 Q. I'm sorry. Were you -- 5 <b>A. I was -- no, no. I list- --</b> 6 Q. Were you not with me when I was reading? 7 <b>A. No. I was listening to you.</b> 8 Q. Okay. 9 <b>A. Okay. Yes. Yes.</b> 10 Q. We were talking about whether or not the IFU 11 contained information and instructions for a physician 12 regarding the fact that the mesh should be placed 13 tension-free, correct? 14 <b>A. I agree that's what you stated, but that's not</b> 15 <b>what this states. It never states placed tension-free.</b> 16 Q. Right. Well, I haven't gotten -- I haven't 17 gotten through the IFU yet. 18 <b>A. Okay. Yes.</b> 19 Q. I'm just noting this section for you. Okay? 20 <b>A. Okay. I will agree with you that that's what</b> 21 <b>this states in this section, but it doesn't say anything</b> 22 <b>about placed.</b> 23 Q. Okay. And this IFU would have been in effect 24 for Mrs. Alonso's operation because that operation was 25 January 19th, 2010, correct?</p>	<p style="text-align: right;">Page 563</p> <p>1 Q. I'm not asking you to agree that this is the 2 version used by Dr. Suarez. We already talked to 3 Dr. Suarez about that. 4 <b>A. Okay.</b> 5 Q. I'm just saying you don't have any reason, 6 sitting here today, to disagree with me that this is 7 probably the version he used. I'm not asking you to 8 agree with me. Do you understand that? 9 <b>A. Yeah. I cannot attest to what version. He</b> 10 <b>would know what version he read. That's all I'm saying.</b> 11 <b>I just can't say it.</b> 12 Q. That's fine. That's fine. And if you go with 13 me to -- we just finished looking at page 4. If you 14 flip to page 5, in all bold, in caps, it says, Implant 15 procedures. Do you see that? 16 <b>A. Yes, I see that.</b> 17 Q. And then there is a section regarding 18 preparation of Avaulta Plus mesh for implantation, 19 correct? 20 <b>A. That is correct.</b> 21 Q. And that provides information to the surgeon 22 regarding what should be done prior to implantation by 23 way of summary, true? 24 <b>A. That is correct.</b> 25 Q. And then -- and then it has a section in bold</p>
<p style="text-align: right;">Page 562</p> <p>1 <b>A. This IFU was in circulation. I don't know</b> 2 <b>what IFU Dr. Suarez was using.</b> 3 Q. Okay. Fair enough. But, as you look at the 4 document, it has a date at the bottom of October 2009 on 5 the first page, correct? 6 <b>A. October of 2009 is when this came out, yes.</b> 7 Q. You don't have any reason, sitting here today, 8 to believe that this was the version of the IFU that was 9 used by Dr. Suarez when he implanted the Avaulta mesh in 10 Mrs. Alonso about a year later? 11 MS. GAYLE: Objection. Asked and answered. 12 BY THE WITNESS: 13 <b>A. I will agree that this was in circulation. I</b> 14 <b>will not agree that that's the version that Dr. Suarez</b> 15 <b>used. Because if the company came to his office, took</b> 16 <b>out all of his old IFUs, and replaced it with the new</b> 17 <b>ones, then I would agree, but I have no support of that.</b> 18 Q. Do you know whether or not an IFU accompanies 19 each and every Bard Avaulta system that is sold and 20 provided to a medical doctor? 21 <b>A. I cannot attest to that. IFUs are usually</b> 22 <b>included, but I don't know what version of -- if he does</b> 23 <b>not do very many of these, perhaps, he's using a product</b> 24 <b>that was, you know, sitting on the shelves for a year</b> 25 <b>because these have long shelf lives.</b></p>	<p style="text-align: right;">Page 564</p> <p>1 for implantation techniques for the Avaulta Plus 2 Biosynthetic Anterior Support System, correct? 3 <b>A. Correct. And I'm trying to correlate that.</b> 4 <b>For my understanding, Alonso had the Avaulta Solo put in</b> 5 <b>her or did she have the Avaulta Classic? Because based</b> 6 <b>upon the operative note, I don't believe it actually</b> 7 <b>states it. I would have to look at what the -- from the</b> 8 <b>records, what he actually -- because I don't recall</b> 9 <b>which one was placed in her.</b> 10 Q. You don't recall which product Mrs. Alonso had 11 implanted in her by Dr. Suarez? 12 <b>A. No. That's what I'm saying. I would want to</b> 13 <b>clarify to make sure we're all on the same page.</b> 14 Q. Okay. If you turn with me to page 6 of 15 Exhibit 30 that we're looking at together -- 16 <b>A. Yes.</b> 17 Q. -- No. 5? 18 <b>A. Yes.</b> 19 Q. If you -- oh, I'm sorry. I'm on the wrong 20 number, No. 6. Number 6 says, Apply traction. It says 21 a number of things, and then the second sentence in 22 No. 6 says, Be sure the graft is tension-free. Do you 23 see that? 24 <b>A. Yes. I am reading over that sentence right</b> 25 <b>now.</b></p>

In Re: CR Bard 200

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<p style="text-align: right;">Page 565</p> <p>1 Q. Okay. This is the second part in the IFU that</p> <p>2 talks about the graft being tension-free?</p> <p>3 <b>A. Correct. With no clarifier what tension-free</b></p> <p>4 <b>actually means.</b></p> <p>5 Q. And then at No. 9, if you go with me to No. 9,</p> <p>6 it has sort of a next step in the surgical procedure, if</p> <p>7 you will. And on the sixth line down, it says, ensure</p> <p>8 the central graft is positioned under the bladder</p> <p>9 without extensive -- excessive tension. Do you see</p> <p>10 that, Doctor?</p> <p>11 <b>A. Yes, I see that.</b></p> <p>12 Q. So that's the third time the IFU is talking</p> <p>13 about not implanting the graft with tension?</p> <p>14 <b>A. No.</b></p> <p>15 Q. It should be tension-free?</p> <p>16 <b>A. I'm sorry. I interrupted you. That's my</b></p> <p>17 <b>fault. No. I disagree with you on the second. Under</b></p> <p>18 <b>point No. 9 of the IFU, it says, without excessive</b></p> <p>19 <b>tension. That means there is tension. There's not</b></p> <p>20 <b>excessive tension. That's different than tension-free.</b></p> <p>21 <b>I completely agree with you on Point No. 6. It states</b></p> <p>22 <b>tension-free. But point No. 9, it's very clear without</b></p> <p>23 <b>excessive tension.</b></p> <p>24 Q. And then, if you go with me to No. 10 on the</p> <p>25 next page, it says, The mesh should be sufficiently</p>	<p style="text-align: right;">Page 567</p> <p>1 <b>A. Well, I think statistically speaking twice</b></p> <p>2 <b>they say avoid excessive tension. One time they say</b></p> <p>3 <b>tension-free. So, again, those are -- they're ambiguous</b></p> <p>4 <b>terms.</b></p> <p>5 Q. You think they're ambiguous?</p> <p>6 <b>A. Yeah. I don't know what excessive tension, if</b></p> <p>7 <b>I -- I am someone, an individual putting these in,</b></p> <p>8 <b>excessive tension means I make it tight, but I just</b></p> <p>9 <b>don't make it really tight. I don't know what that</b></p> <p>10 <b>means.</b></p> <p>11 Q. You've never implanted one of these devices as</p> <p>12 we've talked about yesterday, correct?</p> <p>13 <b>A. I have not implanted, in a live human being,</b></p> <p>14 <b>an Avaulta Plus.</b></p> <p>15 Q. Do you know if Dr. Suarez thought these</p> <p>16 instructions were vague or ambiguous in any way?</p> <p>17 MS. GAYLE: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A. I would have -- I would have to look at his</b></p> <p>20 <b>deposition. I don't recall what he said.</b></p> <p>21 Q. Do you think if a doctor, a surgeon about to</p> <p>22 use the product, thought that these instructions were</p> <p>23 vague or ambiguous in any way, do you think that doctor</p> <p>24 could ask for further information or clarification from</p> <p>25 Bard?</p>
<p style="text-align: right;">Page 566</p> <p>1 anchored to stabilize it during tissue ingrowth. So</p> <p>2 that indicates the anticipated and normal sequence of</p> <p>3 tissue ingrowth in the mesh product, true?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A. To me that's telling me they're trying to</b></p> <p>7 <b>prevent a way to keep this thing from folding and</b></p> <p>8 <b>scarring up.</b></p> <p>9 Q. And then the second sentence says, Additional</p> <p>10 sutures may be used to secure the mesh tension-free. Do</p> <p>11 you see that?</p> <p>12 <b>A. Yes. And then it goes down below. It says,</b></p> <p>13 <b>Caution, excessive tension should be avoided. Again, it</b></p> <p>14 <b>doesn't say tension-free. It says excessive tension.</b></p> <p>15 Q. Right. So that was my next point to you. And</p> <p>16 then there's a caution underneath No. 10. And, it</p> <p>17 reads, as you've started to indicate, Caution, excessive</p> <p>18 tension should be avoided on the mesh and suture</p> <p>19 attachment points to account for wound shrinkage during</p> <p>20 the healing process. Did I read that correctly?</p> <p>21 <b>A. That is what they state.</b></p> <p>22 Q. So the IFU for the Bard Avaulta product</p> <p>23 indicates that it should be tension-free. It should be</p> <p>24 implanted tension-free and excessive tension should be</p> <p>25 avoided?</p>	<p style="text-align: right;">Page 568</p> <p>1 MS. GAYLE: Objection. Form. Calls for</p> <p>2 speculation.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. I think it leaves open the room for a surgeon</b></p> <p>5 <b>looking at this and says, who is doing their due</b></p> <p>6 <b>diligence and reading over this, says avoid excessive</b></p> <p>7 <b>tension. Okay. I'll avoid excessive tension. But it</b></p> <p>8 <b>doesn't say what excessive tension is. Does it say it</b></p> <p>9 <b>would be nice if they prevent the tissues from being</b></p> <p>10 <b>bent or pressure on the tissue? But, again, it just</b></p> <p>11 <b>says excessive tension.</b></p> <p>12 Q. Would you agree with me, Doctor, obviously, if</p> <p>13 a surgeon about to implant this device has any sort of</p> <p>14 ambiguity or it's unclear to that doctor what he or she</p> <p>15 needs to do, that that doctor should ask the question</p> <p>16 before implanting the device, that would be good medical</p> <p>17 practice?</p> <p>18 MS. GAYLE: Objection. Form. Speculation.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. But if -- if the doctor has done their work,</b></p> <p>21 <b>they feel comfortable doing their procedure, then they</b></p> <p>22 <b>read this, without objective data, they won't</b></p> <p>23 <b>necessarily know what excessive tension is.</b></p> <p>24 Q. Well, and if they don't, they should ask a</p> <p>25 question of the device manufacturer, correct?</p>



<p style="text-align: right;">Page 569</p> <p>1 <b>A. No. But excessive tension might be then they</b>  2 <b>might think about it and say, Okay, I see that. Let's</b>  3 <b>make sure this is not cranked up really high so that the</b>  4 <b>bladder is elevated up significantly. I will prevent</b>  5 <b>that. I won't put excessive tension on it.</b>  6 Q. Would you agree with me that it's the  7 responsibility of a pelvic floor surgeon to understand  8 proper surgical technique when implanting a medical  9 device?  10 <b>A. I agree with you completely. And what I'm</b>  11 <b>saying is, without objective data to go off of, this is</b>  12 <b>subjective. And they may look at it. They may think</b>  13 <b>about it. They're doing the responsible thing. They</b>  14 <b>say, okay, I'll avoid excessive tension. That's</b>  15 <b>subjective. It's not an objective term.</b>  16 Q. If you look with me to what we've marked as  17 Exhibit 31, that's the operative report for Dr. Suarez  18 for the surgical procedure on Mrs. Alonso on July 19th,  19 2010?  20 <b>A. Correct.</b>  21 Q. And have you looked at this document before,  22 Dr. Elliott?  23 <b>A. Yes. When I did the original IME, I reviewed</b>  24 <b>this.</b>  25 Q. Okay. Does this document indicate to you that</p>	<p style="text-align: right;">Page 571</p> <p>1 <b>have to answer what that means.</b>  2 Q. Is there any indication in the operative  3 report that he used any type of tacking or sutures to  4 prevent any migration or curling of the mesh?  5 <b>A. No. That's why I stated. I do not see, in</b>  6 <b>his note -- it does not appear that he recorded anything</b>  7 <b>about tacking it down. He would be the best one to</b>  8 <b>answer that question, not me. But I do not -- to answer</b>  9 <b>your question, I do not see it in the note.</b>  10 Q. And if the implanting surgeon, Dr. Suarez,  11 didn't use any sutures or other methods for tacking it  12 down, that may, in fact, have resulted in migration or  13 erosion or curling of the mesh, true?  14 MS. GAYLE: Objection. Form.  15 BY THE WITNESS:  16 <b>A. It would not affect the arms of the mesh. The</b>  17 <b>proximal or distal portion of it, possibly. But I don't</b>  18 <b>know. I have not heard any data or seen any studies</b>  19 <b>whether or not tacking actually correlates to any</b>  20 <b>success. All I can state is, in this note, it does not</b>  21 <b>appear he did any tacking stitches.</b>  22 Q. Would you agree with me that it's possible  23 that due to the lack of tacking of the mesh, that that's  24 why Mrs. Alonso experienced issues with exposure or  25 erosion?</p>
<p style="text-align: right;">Page 570</p> <p>1 Dr. Suarez implanted the mesh under tension and without  2 any proper tacking to prevent migration or curling of  3 the mesh?  4 <b>A. Let me read over it here. Okay. I've</b>  5 <b>finished reading it. I had to determine what segment</b>  6 <b>was what because obviously he performed two different</b>  7 <b>procedures. So the first paragraph of the description</b>  8 <b>of the procedure is the POP, the pelvic organ prolapse.</b>  9 <b>The second part appears to be the urethral sling.</b>  10 Q. And, after reading this, Doctor, does this  11 indicate to you that Dr. Suarez implanted the mesh under  12 tension and did not use any type of tacking as indicated  13 in the IFU to prevent any migration or curling of the  14 mesh?  15 MS. GAYLE: Objection. Form.  16 BY THE WITNESS:  17 <b>A. I do not see, in the dictation, that he states</b>  18 <b>that it was tacked down. Regard- -- so that's point</b>  19 <b>number one. Regarding the tension placed on it, he's</b>  20 <b>using the term vaginal tape, which I'm understanding</b>  21 <b>that is the Avaulta mesh, applied positive pressure</b>  22 <b>against the posterior bladder wall. So I don't -- I</b>  23 <b>don't know what he means by that, applied positive</b>  24 <b>pressure against it. So not to avoid you, I just don't</b>  25 <b>know what that means. He would be the one who would</b></p>	<p style="text-align: right;">Page 572</p> <p>1 MS. GAYLE: Objection. Form. Objection.  2 Mischaracterizes evidence.  3 BY THE WITNESS:  4 <b>A. I can't -- again, I would have to -- important</b>  5 <b>to go off of what the data is out there. I don't know</b>  6 <b>of any data out there, objective studies, showing that</b>  7 <b>that makes a difference at all. It does not correlate</b>  8 <b>to what the IFU states. But does that correlate it to</b>  9 <b>real life? I don't know that.</b>  10 Q. The surgical technique followed by Dr. Suarez  11 is not consistent with what the IFU instructs as you  12 just said, correct?  13 MS. GAYLE: Objection. Form. Mischaracterizes his  14 testimony.  15 BY THE WITNESS:  16 <b>A. On that one aspect of not placing the tacking</b>  17 <b>stitches, that was not done as is stated in the IFU.</b>  18 <b>Whether or not that correlates to complications, I can't</b>  19 <b>answer that.</b>  20 Q. Did you -- so then you didn't consider that  21 issue, Dr. Suarez's surgical technique which is contrary  22 to the IFU, in reaching your opinions with respect to  23 Mrs. Alonso's complications?  24 MS. GAYLE: Objection. Form. Objection,  25 mischaracterizes his testimony. And objection,</p>

<p style="text-align: right;">Page 573</p> <p>1 mischaracterizes the evidence.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. No. What I can state is, I cannot go off of</b></p> <p>4 <b>objective studies, papers looking at whether or not</b></p> <p>5 <b>tacking down correlates to any of those issues as</b></p> <p>6 <b>discussed in the IFU.</b></p> <p>7 Q. Can you tell me whether or not it's possible</p> <p>8 it could have resulted in some of the complications</p> <p>9 experienced by Mrs. Alonso?</p> <p>10 MS. GAYLE: Objection. Form. Objection. As I've</p> <p>11 stated before, mischaracterizes evidence.</p> <p>12 Mischaracterizes testimony. Mischaracterizes</p> <p>13 Dr. Suarez's testimony. And the witness would like</p> <p>14 knowledge. Just because this one page doesn't have it</p> <p>15 on there does not mean that it's not in evidence</p> <p>16 elsewhere.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A. To answer your question, I have no objective</b></p> <p>19 <b>data whether or not tacking actually plays a role in</b></p> <p>20 <b>folding, erosion, extrusion.</b></p> <p>21 Q. Well, Doctor, I'm not -- I'm not a doctor, and</p> <p>22 I wouldn't pretend to be a medical doctor. But tacking</p> <p>23 is included as an instruction in the IFU. And if one</p> <p>24 doesn't tack down the mesh, even a layperson could</p> <p>25 understand that it may move or fold or roll, aren't</p>	<p style="text-align: right;">Page 575</p> <p>1 report beginning on the bottom of page 8 and going to</p> <p>2 page 11?</p> <p>3 <b>A. Correct. Okay.</b></p> <p>4 Q. Okay. So, just for the record, beginning on</p> <p>5 page 8, on the entirety of page 9, the entirety of Page</p> <p>6 10, and then maybe half of page 11, this is about two</p> <p>7 and a half pages of all of the things you think that</p> <p>8 Bard should have included in the IFU for the Avaulta</p> <p>9 product. Is that a fair summary?</p> <p>10 <b>A. That's correct.</b></p> <p>11 Q. And that's your opinion, that all of the</p> <p>12 things on two and a half pages here in your report,</p> <p>13 should have been included in the IFU?</p> <p>14 <b>A. That is correct.</b></p> <p>15 Q. And I think it's also your opinion that</p> <p>16 Mrs. Alonso was not able to make an informed decision</p> <p>17 about her use of transvaginal mesh because Bard failed</p> <p>18 to disclose these risks?</p> <p>19 <b>A. I say it's a combination of things that,</b></p> <p>20 <b>because Dr. Suarez was not fully informed, subsequently</b></p> <p>21 <b>he was not able to fully inform Mrs. Alonso.</b></p> <p>22 Q. Okay. And it's your opinion that, if</p> <p>23 Dr. Suarez was informed in the IFU of all of these</p> <p>24 risks, then he would have been better able to inform</p> <p>25 Mrs. Alonso; is that your opinion?</p>
<p style="text-align: right;">Page 574</p> <p>1 those possibilities, things that may occur, if a mesh is</p> <p>2 not properly tacked down as instructed in the IFU?</p> <p>3 MS. GAYLE: Object to form.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. I disagree completely because I am a surgeon</b></p> <p>6 <b>and I have read the IFUs and the studies on other</b></p> <p>7 <b>products like Prolift, Apogee, and they have nothing</b></p> <p>8 <b>about tacking down. And their products have very high</b></p> <p>9 <b>incidence of erosion, scarring, and things. So just</b></p> <p>10 <b>because this one says it, I don't know.</b></p> <p>11 <b>Also, I have a lot of data showing impaired</b></p> <p>12 <b>healing with the presence of any polypropylene,</b></p> <p>13 <b>especially if there is collagen. So I have data for</b></p> <p>14 <b>that. What I'm saying is, I have no data to go off of</b></p> <p>15 <b>that tacking down the mesh changes the erosion. If you</b></p> <p>16 <b>have data, I would like to see it. I will keep an open</b></p> <p>17 <b>mind.</b></p> <p>18 BY MS. GEIST:</p> <p>19 Q. Let me -- let me move, Doctor, to page 8 of</p> <p>20 your report, if you have your expert report in front of</p> <p>21 you.</p> <p>22 <b>A. I have it here.</b></p> <p>23 Q. And, again, Doctor, I'm going to try and</p> <p>24 summarize, for purposes of efficiency, your opinions</p> <p>25 which are contained in Mrs. Alonso's case-specific</p>	<p style="text-align: right;">Page 576</p> <p>1 <b>A. If he were fully aware of the frequency and</b></p> <p>2 <b>the severity and the permanence of these complications,</b></p> <p>3 <b>including, you know, all that's listed there, he would</b></p> <p>4 <b>have been able to better inform Mrs. Alonso who would</b></p> <p>5 <b>then have been able to better make a decision.</b></p> <p>6 Q. Now, you say, on page 8, at the bottom, that</p> <p>7 all of the risks that you list on the next two and a</p> <p>8 half pages were known, but Mrs. Alonso was not informed</p> <p>9 of these risks on her informed consent. Do you see</p> <p>10 that?</p> <p>11 <b>A. Okay. I'm sorry. You're on the bottom of</b></p> <p>12 <b>page 8.</b></p> <p>13 Q. I'm on the bottom of page 8.</p> <p>14 <b>A. The paragraph starting with since Bard knew;</b></p> <p>15 <b>is that correct?</b></p> <p>16 Q. Correct.</p> <p>17 <b>A. Okay. I'm sorry. Can you repeat the</b></p> <p>18 <b>question?</b></p> <p>19 Q. Sure. So, in the last sentence of this</p> <p>20 paragraph, you say, The following lists of risks that</p> <p>21 were known, but Mrs. Alonso was not informed of on her</p> <p>22 informed consent, correct?</p> <p>23 <b>A. Correct. That's what it states.</b></p> <p>24 Q. Did you look at the informed consent in</p> <p>25 Mrs. Alonso's case as part of your review of her medical</p>



<p style="text-align: right;">Page 577</p> <p>1 records?</p> <p>2 <b>A. Yes. I was sent that.</b></p> <p>3 Q. And there was no information on an informed</p> <p>4 consent about the risk of erosion or pain or dyspareunia</p> <p>5 associated with the Avaulta product, true?</p> <p>6 MS. GAYLE: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 <b>A. I'd have to see that informed consent. I</b></p> <p>9 <b>can't recall that one.</b></p> <p>10 Q. Whose responsibility is it to provide the</p> <p>11 informed consent; Bard's, a medical device manufacturer,</p> <p>12 or the doctor, Dr. Suarez, in this case?</p> <p>13 <b>A. The informed consent is based upon -- the</b></p> <p>14 <b>informed consent is based upon the information that the</b></p> <p>15 <b>surgeon has gained from multiple different sources,</b></p> <p>16 <b>including the IFU.</b></p> <p>17 Q. Okay. So it's not -- you would agree with me</p> <p>18 it's not Bard's responsibility to put particular</p> <p>19 language in an informed consent. The doctor drafts the</p> <p>20 informed consent for his or her patient, true?</p> <p>21 <b>A. I disagree with that. Bard has a</b></p> <p>22 <b>responsibility to provide to the doctors all known risks</b></p> <p>23 <b>regardless of severity and to list them for the doctor.</b></p> <p>24 <b>The doctor's then responsibility is to take that</b></p> <p>25 <b>information, to trust it being accurate, and then to</b></p>	<p style="text-align: right;">Page 579</p> <p>1 <b>A. Mentions the same thing, yes. The doctor has</b></p> <p>2 <b>to take all of the available data that is provided to</b></p> <p>3 <b>him from the company and then inform the patient.</b></p> <p>4 Q. So let's assume that all of the information on</p> <p>5 the two and a half pages that you have here in your</p> <p>6 report was provided by Bard to Dr. Suarez. Okay?</p> <p>7 <b>A. I'm supposed to assume that?</b></p> <p>8 Q. Yeah. Let's assume that. Let's assume all of</p> <p>9 the information that you say should have been put in the</p> <p>10 IFU for the Avaulta product was provided by Bard to</p> <p>11 Dr. Suarez?</p> <p>12 <b>A. If all of those, however many --</b></p> <p>13 MS. GAYLE: I'm sorry. There's --</p> <p>14 BY MS. GEIST:</p> <p>15 Q. There is no question yet.</p> <p>16 MS. GAYLE: There is no question pending, Doctor.</p> <p>17 BY MS. GEIST:</p> <p>18 Q. Just assume -- just assume with me all of that</p> <p>19 information was given to Dr. Suarez, okay?</p> <p>20 <b>A. Okay.</b></p> <p>21 Q. And all of this information on the two and a</p> <p>22 half pages you say, Dr. Elliott, is information that</p> <p>23 Bard knew about and Bard purposely didn't put it in the</p> <p>24 IFU, didn't communicate it to doctors; is that a fair</p> <p>25 summary? Bard should have done this, Bard knew about</p>
<p style="text-align: right;">Page 578</p> <p>1 <b>properly inform the patient.</b></p> <p>2 Q. So the doctor's responsibility is to put</p> <p>3 together the informed consent and provide the</p> <p>4 risk-benefit analysis to the patient. That's the</p> <p>5 doctor's role, correct? I mean, there's nothing</p> <p>6 controversial about what I'm asking you here. That's</p> <p>7 the doctor's role?</p> <p>8 <b>A. The doctor's role is just as I stated. The</b></p> <p>9 <b>doctor has to take all available information on a</b></p> <p>10 <b>product and surgery and then to adequately inform and</b></p> <p>11 <b>thoroughly inform the patient.</b></p> <p>12 Q. All right. So I think we're saying the same</p> <p>13 thing. You don't expect Bard to be sitting down with a</p> <p>14 particular patient and talking about the particular</p> <p>15 risks and benefits of the medical device. The doctor's</p> <p>16 role is to have that conversation with his or her</p> <p>17 patient. Do you agree with me on that?</p> <p>18 <b>A. Yeah. Bard's role is to provide all known</b></p> <p>19 <b>complications regardless of severity, and then the</b></p> <p>20 <b>doctor's role is to be in the room alone with the</b></p> <p>21 <b>patient and family. Bard has no role inside that office</b></p> <p>22 <b>interaction.</b></p> <p>23 Q. Right. It's the doctor's job to obtain the</p> <p>24 informed consent from his or her patient for the</p> <p>25 surgical procedure, correct?</p>	<p style="text-align: right;">Page 580</p> <p>1 these risks and didn't communicate it to doctors?</p> <p>2 MS. GAYLE: Objection. Form.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. Yeah. You're asking me to assume something,</b></p> <p>5 <b>and then I'm kind of not following you because it's a</b></p> <p>6 <b>complicated question. You're asking me to assume Bard</b></p> <p>7 <b>told everybody and I lost you.</b></p> <p>8 Q. Yeah. Let me go back. You're saying that</p> <p>9 Bard knew about all of these risks and Bard should have</p> <p>10 informed Dr. Suarez, or any other doctor, about all of</p> <p>11 these risks, Bard failed to do this, Bard knew certain</p> <p>12 information, and they failed to put it in the IFU?</p> <p>13 <b>A. They failed to adequately put it in the IFU.</b></p> <p>14 <b>I'll agree with that.</b></p> <p>15 Q. Okay. On that point, Doctor, did you ever</p> <p>16 review any FDA regulations or rules on what needs to go</p> <p>17 into an IFU before getting involved in this litigation?</p> <p>18 MS. GAYLE: Objection to that question. That was</p> <p>19 covered yesterday in his general testimony.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. That wasn't specifically. The question was,</p> <p>22 before you got involved in this litigation, did you ever</p> <p>23 review any FDA rules or regulations relating to what</p> <p>24 should or should not be put into a medical device</p> <p>25 instructions for use?</p>

<p style="text-align: right;">Page 581</p> <p>1 MS. GAYLE: Objection. Again, I believe that was</p> <p>2 covered yesterday.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. Do I answer? I mean --</b></p> <p>5 Q. It's a different question, and I'm happy to</p> <p>6 compare the transcripts. But the question was specific.</p> <p>7 Before this litigation, had you ever read or acquainted</p> <p>8 yourself with the FDA rules and regulations regarding</p> <p>9 what information needs to be put or not included in an</p> <p>10 IFU?</p> <p>11 MS. GAYLE: You may answer that question subject to</p> <p>12 my objection.</p> <p>13 BY THE WITNESS:</p> <p>14 <b>A. I guess I'm somewhat confused. I thought</b></p> <p>15 <b>yesterday was the -- all of this. Now we're going back</b></p> <p>16 <b>to the general report. I can't recall all of the</b></p> <p>17 <b>documents. I'm involved in reviewing 30 different IFUs.</b></p> <p>18 <b>I can pull up the notes as far as what IFUs I reviewed.</b></p> <p>19 <b>I can't recall when I first saw FDA guidelines. You</b></p> <p>20 <b>know, in 2008, when the first FDA warning came out, I</b></p> <p>21 <b>reviewed the things then. In 2011, I reviewed it.</b></p> <p>22 <b>So I can't recall when I first became aware of</b></p> <p>23 <b>various different FDA -- I'm sure, over the course of</b></p> <p>24 <b>this litigation, my understanding of the regulation</b></p> <p>25 <b>process has increased. I'm not going to deny that. I</b></p>	<p style="text-align: right;">Page 583</p> <p>1 <b>first looked at any, like the FDA Blue Book. I don't</b></p> <p>2 <b>know when that first was. I wouldn't be able to tell</b></p> <p>3 <b>you with any specific accuracy. That FDA Blue Book is</b></p> <p>4 <b>available online.</b></p> <p>5 Q. And you can't tell me whether or not you first</p> <p>6 looked at that before you got involved as an expert in</p> <p>7 the litigation?</p> <p>8 MS. GAYLE: Objection. Asked and answered and</p> <p>9 discussed yesterday. I'm going to instruct him not to</p> <p>10 go over this territory, which was went over yesterday.</p> <p>11 I think we're burning time on this issue and it's</p> <p>12 duplicate. And, you know, Judge Goodwin does not like</p> <p>13 duplicative testimony.</p> <p>14 BY MS. GEIST:</p> <p>15 Q. It's not. I never asked you yesterday about</p> <p>16 did you review any FDA regulations, rules or guidance,</p> <p>17 before you got involved as an expert in the litigation.</p> <p>18 I did not ask that question yesterday. That's why I'm</p> <p>19 asking it today.</p> <p>20 MS. GAYLE: And it should have been answered,</p> <p>21 Counsel, because that's a general question that went to</p> <p>22 his general opinions yesterday. We covered the Blue</p> <p>23 Book yesterday. He answered questions. If you failed</p> <p>24 to ask a question yesterday, it's our position that it's</p> <p>25 a question that's lost because it was a general</p>
<p style="text-align: right;">Page 582</p> <p>1 <b>don't recall when I first saw what was required. I was</b></p> <p>2 <b>always under the impression everything had to be told to</b></p> <p>3 <b>the doctor on the IFU.</b></p> <p>4 Q. And I understand your impression, but my</p> <p>5 question was, before you got involved as an expert for</p> <p>6 plaintiffs in the pelvic mesh litigation, did you ever</p> <p>7 go and review and research the FDA regulations, rules</p> <p>8 and guidance documents, about what needs to go into a</p> <p>9 label or not?</p> <p>10 MS. GAYLE: My objection is reiterated. Again, I</p> <p>11 think this goes to yesterday's testimony as well as</p> <p>12 another objection because he's asked and answered the</p> <p>13 question.</p> <p>14 BY THE WITNESS:</p> <p>15 <b>A. Okay. As of day one of medical school</b></p> <p>16 <b>residency staff, I was -- and I'll answer your question.</b></p> <p>17 <b>I was under the understanding the IFU had to tell me</b></p> <p>18 <b>everything about the product. That was my</b></p> <p>19 <b>understanding. Then, as I got involved in this</b></p> <p>20 <b>litigation and looking at various different things and</b></p> <p>21 <b>digging deeper, then I'm finding out that that</b></p> <p>22 <b>understanding was correct.</b></p> <p>23 <b>However, again, in 2008 and 2011, when the FDA</b></p> <p>24 <b>started coming out with these warnings, that's when I</b></p> <p>25 <b>started looking into this. So I can't tell you when I</b></p>	<p style="text-align: right;">Page 584</p> <p>1 question. You can't rehash general today when he's</p> <p>2 sitting here on case specifics. You're not asking him</p> <p>3 anything about the Blue Book in relation to these three</p> <p>4 plaintiffs.</p> <p>5 MS. GEIST: Well, I'm going to object. You should</p> <p>6 make your objection to form. If you want to raise it in</p> <p>7 a motion, that's fine. Speaking objections are not</p> <p>8 allowed. We went through this yesterday with other</p> <p>9 counsel.</p> <p>10 And this is a specific point in Dr. Elliott's</p> <p>11 case-specific report that goes on for four pages. And</p> <p>12 it's specifically tied to Mrs. Alonso, because</p> <p>13 Dr. Elliott opines, in his report, that all of these</p> <p>14 risks should have been in the IFU and Mrs. Alonso was</p> <p>15 not informed of these risks because Bard failed to</p> <p>16 provide these risks to her surgeon, Dr. Suarez.</p> <p>17 MS. GAYLE: And we'll just take it up in motion</p> <p>18 practice.</p> <p>19 MS. GEIST: That's fine.</p> <p>20 MS. GAYLE: But, again, our objection is</p> <p>21 reiterated. This is a general opinion. If you have</p> <p>22 opinions to these people, ask a question to these</p> <p>23 people.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. And that's what this is all about,</p>

<p style="text-align: right;">Page 585</p> <p>1 Mrs. Alonso. So can you answer my last question,  2 Doctor?  3 MS. GEIST: If the court reporter could read it  4 back for him.  5 BY THE WITNESS:  6 A. No. I recall the question. You're asking me  7 to speculate. If I had to give a time frame of first  8 looking into specific FDA regulations, that would be  9 when I was contacted by Dr. Michael Carome of Public  10 Citizen because he was getting involved as far as  11 drafting that copy to the F- -- yeah, to the FDA. And  12 that's probably when I first would have looked at that  13 document. And that was in -- it was signed in August.  14 That process started, probably, in June, June of 2011.  15 Q. Thank you. So, now, Doctor, getting back to  16 my original question, let's assume that all of the  17 information that you say Bard knew about and, therefore,  18 should have put in the IFU, this two and a half pages,  19 let's assume, for the purposes of this question, that  20 Dr. Suarez was informed by Bard of everything you lay  21 out here in your two and a half pages. Okay?  22 A. Okay.  23 Q. Can you assume that for me?  24 A. I can assume that, yes.  25 Q. Okay. Even if all of this information was</p>	<p style="text-align: right;">Page 587</p> <p>1 BY THE WITNESS:  2 A. I cannot speculate what Dr. Suarez would do.  3 I can speculate -- I -- beyond speculate, I could tell  4 you what I would do and what a reasonable colleague of  5 mine would do. I can't speak for Dr. Suarez.  6 Dr. Suarez would be the best one to answer that  7 question.  8 Q. Well, you told me you read Ms. Alonso's  9 deposition testimony, right?  10 A. Correct.  11 Q. Do you recall her testimony that she was not  12 informed of any of the risks associated with  13 transvaginal mesh?  14 A. I do recall her saying that. In my  15 experience, sometimes individuals forget things over  16 time. I know what she stated.  17 Q. Well, would you agree with me that there is  18 nowhere in Dr. Suarez's records or the informed consent  19 to establish that he provided her with any of the risks  20 of the implantation of transvaginal mesh to Mrs. Alonso?  21 MS. GAYLE: Objection, form.  22 BY THE WITNESS:  23 A. That's why I stated earlier I would want to  24 see, again, the clinical notes and specifically the  25 informed consent. And then that also does not entail</p>
<p style="text-align: right;">Page 586</p> <p>1 provided to Dr. Suarez, how do you know, to a reasonable  2 degree of medical probability or certainty, that  3 Dr. Suarez would have provided any of that information  4 to Mrs. Alonso?  5 A. Well, you're asking me to theorize. You're  6 asking me, number one, to make a huge assumption that  7 Dr. Suarez would have provided -- been provided an  8 honest evaluation of risks, lifelong complications, and  9 a reasonable doctor would have then relayed that on to  10 patients. I cannot speak for him. I would have told  11 the patients all of that data because I wanted a fully  12 informed patient. I cannot speculate what Dr. Suarez  13 would do. That would be a best question for him.  14 Q. So, sitting here today, you can't say that had  15 Bard provided all of this information to Dr. Suarez,  16 Dr. Suarez would have provided it to Mrs. Alonso?  17 MS. GAYLE: Objection. Form.  18 BY THE WITNESS:  19 A. I can't speak to what Dr. Suarez would do. I  20 can speak to what I would do and what I feel a  21 reasonable surgeon would do.  22 Q. Can we agree, Dr. Elliott, that Dr. Suarez  23 likely would not have provided all of this information  24 to Mrs. Alonso?  25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 588</p> <p>1 what actually went on in the office. And if he were  2 under the impression, after reading the IFU, that these  3 risks are minimal, he might have downplayed it.  4 Q. Did you see any evidence in the records that  5 Dr. Suarez talked to Mrs. Alonso about risks like  6 erosion, pelvic pain, and dyspareunia associated with  7 the implant of a transvaginal mesh product?  8 A. Yeah. I don't recall, and that's why I'm  9 asking to see those records again so we can go over  10 that, what was done on multiple clinic visits and at the  11 formal informed consent.  12 Q. So I just want to make sure I'm clear. There  13 is no -- you don't have any evidence, sitting here  14 today, Dr. Elliott, that Dr. Suarez would have passed on  15 any of this information that you say should have been  16 included in the IFU?  17 MS. GAYLE: Objection.  18 BY MS. GEIST:  19 Q. That he would have passed any of it on to  20 Mrs. Alonso?  21 MS. GAYLE: Object.  22 BY MS. GEIST:  23 Q. Would you agree with me?  24 MS. GAYLE: Objection, form. Objection,  25 mischaracterizes evidence.</p>

<p style="text-align: right;">Page 589</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A. Well, all I can state -- again, I cannot speak</b></p> <p>3 <b>for Dr. Suarez. He is the one who needs to address that</b></p> <p>4 <b>question. A reasonable surgeon would relay on to a</b></p> <p>5 <b>patient, if he or she is fully knowledgeable of all of</b></p> <p>6 <b>the risks, you have to relay all of those risks to the</b></p> <p>7 <b>patient.</b></p> <p>8 Q. Well, would a reasonable surgeon relay to a</p> <p>9 patient who is considering having a transvaginal mesh</p> <p>10 device implanted in her body, would a reasonable surgeon</p> <p>11 talk about risks such as erosion, pain, and dyspareunia?</p> <p>12 <b>A. I can speak for myself. I would.</b></p> <p>13 Q. And those are all risks that are in the Bard</p> <p>14 Avaulta IFU, are they not?</p> <p>15 <b>A. I would have to look at the IFU and see how</b></p> <p>16 <b>they state it. Because if -- if a surgeon is looking at</b></p> <p>17 <b>his frame of reference being native procedures and he</b></p> <p>18 <b>sees pain, he's thinking and correlating that to native</b></p> <p>19 <b>procedures, which is short-term, so pain, dyspareunia,</b></p> <p>20 <b>all of those things. So, again, I can't speak to what</b></p> <p>21 <b>that surgeon's frame of reference is. Again, he would</b></p> <p>22 <b>be the best one to answer that.</b></p> <p>23 Q. Well, referring back to the IFU that we marked</p> <p>24 as Exhibit 30, Doctor, under Adverse Reactions, on page</p> <p>25 5 of the IFU, the Adverse Reactions section of the IFU</p>	<p style="text-align: right;">Page 591</p> <p>1 deposition. You were prepared to come here and talk</p> <p>2 about Mrs. Alonso's case, correct?</p> <p>3 <b>A. Yes. I had over a thousand pages of documents</b></p> <p>4 <b>to review, and I cannot remember every single word. And</b></p> <p>5 <b>so that's why I would like to just see what was stated</b></p> <p>6 <b>on his informed consent.</b></p> <p>7 Q. So, sitting here now, you can't tell me</p> <p>8 whether or not Dr. Suarez informed Mrs. Alonso of at</p> <p>9 least some of the risks that are included here in the</p> <p>10 adverse reaction section of the IFU?</p> <p>11 <b>A. I have the understanding a deposition is not</b></p> <p>12 <b>memory test. This is very detailed issues, and that's</b></p> <p>13 <b>why I would like to see the informed consent. It seems</b></p> <p>14 <b>fairly basic. I asked for the operative report and I</b></p> <p>15 <b>got that. And so I would like to see the informed</b></p> <p>16 <b>consent and then we can logically go through it. And</b></p> <p>17 <b>then I can disagree -- or, excuse me, agree or disagree</b></p> <p>18 <b>with you.</b></p> <p>19 Q. If -- if Dr. Suarez did not inform Mrs. Alonso</p> <p>20 of some of the potential adverse events or complications</p> <p>21 associated with transvaginal mesh, would that be acting</p> <p>22 within the standard of care?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 <b>A. I don't know as far as standard of care. The</b></p>
<p style="text-align: right;">Page 590</p> <p>1 from Bard informs a surgeon that complications</p> <p>2 associated even with the proper implantation of the</p> <p>3 Avaulta Plus Biosynthetic Support System include, and</p> <p>4 what's listed below are a number of different things.</p> <p>5 And what's included is extrusion, erosion, inflammation,</p> <p>6 pain, dyspareunia, scarification, among other things.</p> <p>7 Those are all -- all included in the adverse reaction</p> <p>8 section of the IFU, true?</p> <p>9 <b>A. Yeah. But, see, we're limited. It talks</b></p> <p>10 <b>about extrusion, but it does not talk about lifelong</b></p> <p>11 <b>risk of extrusion. It does not give you any qualifiers</b></p> <p>12 <b>of the extent and the severity of the problem.</b></p> <p>13 Q. Understood. But there is no evidence in this</p> <p>14 case, from the informed consent documents or the records</p> <p>15 from Dr. Suarez, that Dr. Suarez even told Mrs. Alonso</p> <p>16 about the potential risks of erosion, pain, or</p> <p>17 dyspareunia?</p> <p>18 MS. GAYLE: Objection.</p> <p>19 BY MS. GEIST:</p> <p>20 Q. Do you agree with me?</p> <p>21 <b>A. Again, I would have to see that -- those</b></p> <p>22 <b>records. I don't recall that specific terminology. I</b></p> <p>23 <b>would have to look at the records.</b></p> <p>24 Q. Well, Doctor, we don't have time for you to go</p> <p>25 through all of the records again here at your</p>	<p style="text-align: right;">Page 592</p> <p>1 <b>purpose of an informed consent is to inform the patient</b></p> <p>2 <b>of risks and have them consent or not.</b></p> <p>3 Q. So -- all right. So setting aside standard of</p> <p>4 care, if Mrs. Alonso's testimony is true that Dr. Suarez</p> <p>5 didn't tell her about any of the potential risks</p> <p>6 associated with the implantation of Bard's Avaulta</p> <p>7 product, that would be something you would be critical</p> <p>8 of with respect to Dr. Suarez?</p> <p>9 MS. GAYLE: Object to form. Objection,</p> <p>10 mischaracterizes evidence and testimony.</p> <p>11 BY MS. GEIST:</p> <p>12 Q. I mean, would that be proper medical care and</p> <p>13 counseling to a patient if Dr. Suarez did not, in fact,</p> <p>14 obtain informed consent from Mrs. Alonso prior to the</p> <p>15 procedure?</p> <p>16 <b>A. In discussion with patients on a daily basis</b></p> <p>17 <b>and providing informed consents to patients on a daily</b></p> <p>18 <b>basis, unfortunately, not everybody remembers all of the</b></p> <p>19 <b>issues that are discussed with them. So, therefore,</b></p> <p>20 <b>that's why I'd have to go down to the -- what the notes</b></p> <p>21 <b>say and what Dr. Suarez says in his deposition.</b></p> <p>22 MS. GEIST: Can we go off the record one</p> <p>23 minute?</p> <p>24 VIDEO TECHNICIAN: We're off the record. The time</p> <p>25 is 11:35 a.m.</p>



In Re: CR Bard 200

Daniel Elliott M.D., Vol. II

11/16/2014

<p style="text-align: right;">Page 593</p> <p>1 (A short recess was had.)</p> <p>2 VIDEO TECHNICIAN: We're back on the record. The</p> <p>3 time is 11:37 a.m.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. Dr. Elliott, had Mrs. Alonso had a native</p> <p>6 tissue repair to resolve her pelvic organ prolapse or an</p> <p>7 abdominal sacrocolpopexy procedure, would you agree with</p> <p>8 me that she could have experienced the same issues with</p> <p>9 pelvic pain and dyspareunia?</p> <p>10 <b>A. No. I disagree.</b></p> <p>11 Q. You disagree. She didn't have -- she wouldn't</p> <p>12 have had any risk of pelvic pain or dyspareunia after</p> <p>13 having a native tissue repair; is that your testimony?</p> <p>14 <b>A. No. My testimony is you have to put the</b></p> <p>15 <b>qualifiers on the location, the degree, the severity,</b></p> <p>16 <b>the inability to cure it. And with a sacrocolpopexy, we</b></p> <p>17 <b>are talking about -- excuse me, with a mesh repair,</b></p> <p>18 <b>we're talking about midvault scarring of the obturator</b></p> <p>19 <b>foramen. The sacrocolpopexy is not even in that region.</b></p> <p>20 <b>The same thing with the native tissue repair. So I</b></p> <p>21 <b>would -- you would have to put the qualifiers on it.</b></p> <p>22 Q. Okay. Well, let me try and put the qualifiers</p> <p>23 on it. If Mrs. Alonso had had a native tissue repair,</p> <p>24 would you agree with me that she still could have</p> <p>25 experienced pelvic pain and dyspareunia?</p>	<p style="text-align: right;">Page 595</p> <p>1 had a native tissue repair or an ASC, an abdominal</p> <p>2 sacrocolpopexy, she could have still experienced some</p> <p>3 degree of pelvic pain and dyspareunia, true?</p> <p>4 MS. GAYLE: Objection. Form. Mischaracterizes his</p> <p>5 testimony.</p> <p>6 BY THE WITNESS:</p> <p>7 <b>A. To a minor and, in my experience, correctible</b></p> <p>8 <b>extent and short-lived and, as far as impact upon</b></p> <p>9 <b>quality of life, minimal, she could have had some</b></p> <p>10 <b>discomfort.</b></p> <p>11 Q. Is it your opinion, Doctor, that every woman</p> <p>12 who has had a native tissue repair or an ASC and who has</p> <p>13 experienced pelvic pain and dyspareunia as a result of</p> <p>14 those surgeries has always had short-term and</p> <p>15 correctible pelvic pain and dyspareunia?</p> <p>16 MS. GAYLE: Objection. Form.</p> <p>17 BY MS. GEIST:</p> <p>18 Q. There is no risk of long-term pelvic pain or</p> <p>19 dyspareunia with either of those surgical procedures?</p> <p>20 MS. GAYLE: Objection. Form. Mischaracterizes his</p> <p>21 testimony and asked and answered yesterday as well as</p> <p>22 today.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. I can state, in my practice now, at a</b></p> <p>25 <b>high-volume tertiary center with highly subspecialized</b></p>
<p style="text-align: right;">Page 594</p> <p>1 <b>A. In my experience, in a high-volume tertiary</b></p> <p>2 <b>center, a member of the International Pelvic Pain</b></p> <p>3 <b>Society, she has the chance of having mild and usually</b></p> <p>4 <b>correctible -- and, in my experience, I have never had</b></p> <p>5 <b>one of permanent -- dyspareunia. That is comparing to</b></p> <p>6 <b>mesh, which is permanent, progressive, and severe.</b></p> <p>7 Q. So she could have still experienced pelvic</p> <p>8 pain and dyspareunia, but it's your opinion that the</p> <p>9 pelvic pain and dyspareunia she's complaining of now is</p> <p>10 more severe and permanent in nature; is that right?</p> <p>11 <b>A. It is more severe. Based upon the data and my</b></p> <p>12 <b>experience, it's progressive. There is no ability to</b></p> <p>13 <b>cure it. So with those qualifiers on there, then I</b></p> <p>14 <b>agree with you.</b></p> <p>15 Q. And you're certainly not going to give an</p> <p>16 opinion that had Mrs. Alonso had a native tissue or an</p> <p>17 ASC procedure, that she would have had no risk of</p> <p>18 experiencing pelvic pain or dyspareunia? You would</p> <p>19 never give that opinion, would you?</p> <p>20 <b>A. I would give the opinion that, in my</b></p> <p>21 <b>experience, I've never once had an individual with this</b></p> <p>22 <b>severe of pain in this location and in a progressive</b></p> <p>23 <b>nature. And in our review of sacrocolpopexies, we've</b></p> <p>24 <b>had zero incidence of pelvic pain.</b></p> <p>25 Q. So the answer to my question is, yes, had she</p>	<p style="text-align: right;">Page 596</p> <p>1 <b>care that I have never once seen an individual with a</b></p> <p>2 <b>native tissue or sacro- -- or sacrocolpopexy procedure</b></p> <p>3 <b>present with severe, debilitating, progressive pain like</b></p> <p>4 <b>I see with the transvaginal mesh kits.</b></p> <p>5 Q. But you're aware, from the literature, if not</p> <p>6 your own personal experience, that women who have had</p> <p>7 native tissue and ASC repairs experience pelvic pain and</p> <p>8 dyspareunia years after those procedures are done?</p> <p>9 You're aware of that, correct?</p> <p>10 MS. GAYLE: Continuing objection. Can I have that</p> <p>11 so I don't have to keep interrupting you on this line of</p> <p>12 questioning? I believe you asked and answered this</p> <p>13 yesterday, Counsel.</p> <p>14 BY MS. GEIST:</p> <p>15 Q. Well, I'm focusing on Mrs. Alonso.</p> <p>16 <b>A. My statement stands as from yesterday and</b></p> <p>17 <b>today. And what I've reiterated is you have to put the</b></p> <p>18 <b>qualifiers on there of the severity, the progressive</b></p> <p>19 <b>nature of it, the life-changing disability. I have</b></p> <p>20 <b>never once, at a high-volume tertiary care center, seen</b></p> <p>21 <b>that. Especially important when you look at the various</b></p> <p>22 <b>different papers out there from Karram, Zimmerman,</b></p> <p>23 <b>Blandon, that we discussed, where they're saying that</b></p> <p>24 <b>these mesh complications require tertiary care.</b></p> <p>25 <b>So I am not seeing the need for these -- for</b></p>

<p style="text-align: right;">Page 597</p> <p>1 <b>tertiary, advanced-level care with these women who</b>  2 <b>received those other types of native repair or</b>  3 <b>sacrocolpopexy.</b>  4 Q. So Mrs. Alonso is complaining of pelvic pain  5 and dyspareunia a few years after her mesh implant  6 procedure, correct?  7 <b>A. That is correct.</b>  8 Q. And is it not established in the literature  9 that women who had a native tissue or ASC repair  10 complain of pelvic pain and dyspareunia years after  11 those procedures as well?  12 <b>A. Again, we keep leaving off those qualifiers.</b>  13 <b>If you give me those qualifiers on there, severe,</b>  14 <b>progressive, debilitating, without a source of cure,</b>  15 <b>then I will agree with you.</b>  16 Q. Had Mrs. Alonso had a transvaginal mesh device  17 implanted by another manufacturer, would you agree with  18 me, Dr. Elliot, that she could have experienced pelvic  19 pain and dyspareunia as a result of that procedure?  20 MS. GAYLE: Objection. Form.  21 BY THE WITNESS:  22  23  24  25</p>	<p style="text-align: right;">Page 599</p> <p>1 <b>opinion, if she had the Avaulta Plus, she's at the</b>  2 <b>highest risk possible of complication with the</b>  3 <b>transvaginal mesh kit.</b>  4 Q. Understood. But we agree that had she used  5 another medical device company's mesh kit, she still  6 could have had the same complications?  7 MS. GAYLE: Objection.  8 BY MS. GEIST:  9 Q. Are we in agreement on that?  10 MS. GAYLE: Objection, form. And objection, calls  11 for speculation.  12 BY THE WITNESS:  13 <b>A. I mean, I think I answered it very well the</b>  14 <b>last time. And, actually, I would like to know. I</b>  15 <b>would like to see in the records, because we must have</b>  16 <b>it somewhere -- I just don't have it off the top of my</b>  17 <b>head -- which product she had put in there. So if she</b>  18 <b>had the Plus or not, because that would help us out.</b>  19 <b>Because if she had the Plus, I will then state that she</b>  20 <b>is at a higher risk for complications.</b>  21 Q. Understood. But she still would have been at  22 risk for the same complications if she had been  23 implanted with another medical device's -- another  24 medical device company's pelvic mesh kit product, true?  25 MS. GAYLE: Objection. Form. Counsel, are you</p>
<p style="text-align: right;">Page 598</p> <p>1 <b>A. And that is theoretical; however, if you look</b>  2 <b>at the data out there, Prolift, Apogee, Perigee,</b>  3 <b>Pinnacle, SIS, severe debilitating pain occurs with</b>  4 <b>those other mesh devices as well as Avaulta.</b>  5 Q. Okay. So, sitting here today, you can't say  6 that Mrs. Alonso's outcome would have been any different  7 had she been implanted with another transvaginal mesh  8 device?  9 MS. GAYLE: Objection.  10 BY MS. GEIST:  11 Q. Is that true?  12 MS. GAYLE: Objection. Form and objection calls  13 for speculation and --  14 BY THE WITNESS:  15 <b>A. That's not necessarily true because remember I</b>  16 <b>just cannot recall, from the literature -- or not,</b>  17 <b>excuse me, not the literature, the medical records which</b>  18 <b>specific Avaulta product she had placed. If she had the</b>  19 <b>Plus, then she has collagen on there so there could be a</b>  20 <b>higher rate of complications with it. The arms are</b>  21 <b>heavier weight with the Avaulta product regardless of</b>  22 <b>which one it is.</b>  23 <b>So I cannot say she would not -- it gets</b>  24 <b>confusing. There is a very good risk she still would</b>  25 <b>have had complications with another mesh kit. In my</b></p>	<p style="text-align: right;">Page 600</p> <p>1 talking about the same exact complications  2 percentage-wise, different? What?  3 BY MS. GEIST:  4 Q. Could Mrs. Alonso still have experienced  5 pelvic pain and dyspareunia if she had been implanted  6 with another medical device company's transvaginal mesh?  7 That's my question.  8 <b>A. My opinion is transvaginal polypropylene mesh</b>  9 <b>for pelvic organ prolapse is bad across the board. Had</b>  10 <b>she had another product in there like Prolift, which</b>  11 <b>there's hundreds and hundreds of papers out on Prolift,</b>  12 <b>perhaps, even more than that, clearly shows devastation</b>  13 <b>in women. Apogee, Perigee, the same thing. Pinnacle,</b>  14 <b>the same thing. And, again, there is another product</b>  15 <b>out there. I can't recall off the top of my head.</b>  16 <b>So, yes, she could have had devastating</b>  17 <b>complications with that. My argument is, is that the</b>  18 <b>Avaulta mesh, the arms are heavyweight, small pore,</b>  19 <b>which data shows that Klosterhalfen and Cobb, et al.,</b>  20 <b>higher rates of complications with those. And, if she</b>  21 <b>had collagen, there's data that show those have impaired</b>  22 <b>healing. So I am -- I am partly agreeing with you,</b>  23 <b>again, with the clarifications in this as I answered</b>  24 <b>here.</b>  25 Q. If -- if Mrs. Alonso's transvaginal mesh was</p>

<p style="text-align: right;">Page 601</p> <p>1 made from a different grade of polypropylene other than</p> <p>2 the Marlex polypropylene used in the Avaulta products,</p> <p>3 can you state, to a reasonable degree of medical</p> <p>4 certainty, that she would not have experienced pelvic</p> <p>5 pain and dyspareunia?</p> <p>6 MS. GAYLE: Objection, form. Objection, calls for</p> <p>7 speculation and assumes facts not in evidence.</p> <p>8 BY THE WITNESS:</p> <p>9 <b>A. Yeah. I'm sorry. Like, as far as a different</b></p> <p>10 <b>grade, you'd have to tell me the weight of it, the pore</b></p> <p>11 <b>size, all of those different factors. Right now, as far</b></p> <p>12 <b>as I know, the Marlex that is used has heavyweight arms.</b></p> <p>13 <b>And so, again, polypropylene, in my -- my opinion, based</b></p> <p>14 <b>upon my evidence and my experience and what we had</b></p> <p>15 <b>mentioned over and over and over, should not be placed</b></p> <p>16 <b>in the vagina on women for pelvic organ prolapse.</b></p> <p>17 Q. But it's okay for the midurethral sling,</p> <p>18 correct?</p> <p>19 MS. GAYLE: Objection.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. As we talked about yesterday?</p> <p>22 MS. GAYLE: Objection. Form. Objection.</p> <p>23 Mischaracterizes testimony and goes into general</p> <p>24 opinions from yesterday.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 603</p> <p>1 clarify, was in response to this specific patient. And</p> <p>2 so we're not reploting general opinions from yesterday.</p> <p>3 MS. GEIST: Right. We're talking about this</p> <p>4 specific patient.</p> <p>5 MS. GAYLE: It's your question. We're doing</p> <p>6 specifics.</p> <p>7 BY MS. GEIST:</p> <p>8 Q. In this specific patient, we already talked</p> <p>9 about the fact that she has the Align sling implanted at</p> <p>10 the same time that she had the Avaulta Plus or Solo</p> <p>11 product implanted, and we don't know which one it is,</p> <p>12 right?</p> <p>13 <b>A. Correct. I know what the Align sling was. We</b></p> <p>14 <b>know that. That's very clear.</b></p> <p>15 Q. But not which Bard POP product?</p> <p>16 <b>A. No. I do not recall what that one is, and the</b></p> <p>17 <b>operative note does not state it.</b></p> <p>18 Q. And --</p> <p>19 <b>A. And those were done at the same procedure,</b></p> <p>20 <b>July 19th, 2010.</b></p> <p>21 Q. And the Align sling that Mrs. Alonso had</p> <p>22 implanted was implanted for the purpose of correcting</p> <p>23 her stress urinary incontinence, correct?</p> <p>24 <b>A. Correct.</b></p> <p>25 Q. That's the indication for that medical device?</p>
<p style="text-align: right;">Page 602</p> <p>1 <b>A. No. What I just said, I had the qualifiers on</b></p> <p>2 <b>there on purpose. The Align sling is heavyweight, small</b></p> <p>3 <b>pore, which we have data from Cobb, Klosterhalfen, are</b></p> <p>4 <b>the two I can remember off the top of my head. My</b></p> <p>5 <b>report has many more. There are known, very clear</b></p> <p>6 <b>complications from that with degradation, contraction,</b></p> <p>7 <b>pain, et cetera. So I personally, in my practice, do</b></p> <p>8 <b>not implant any transvaginal mesh.</b></p> <p>9 Q. But you understand, and I don't want to replot</p> <p>10 yesterday at all, but you understand that other pelvic</p> <p>11 floor surgeons continue to believe in and implant the</p> <p>12 midurethral polypropylene sling like the Align product,</p> <p>13 and you haven't come out and sent a separate letter to</p> <p>14 the FDA seeking the removal of that type of product from</p> <p>15 the market like you did with the POP products, true?</p> <p>16 MS. GAYLE: Objection. I'm going to instruct him</p> <p>17 not to answer that as that is exactly reploting</p> <p>18 yesterday.</p> <p>19 MS. GEIST: Well, the doctor brought it up. I</p> <p>20 think it's legitimate. If he's going to raise it, then</p> <p>21 I can ask a question in response. So I would like to</p> <p>22 have an answer subject to your objection.</p> <p>23 MS. GAYLE: But you, yourself, admitted that was</p> <p>24 reploting yesterday and it was a general question. And</p> <p>25 so I think his answer or his question, and he can</p>	<p style="text-align: right;">Page 604</p> <p>1 <b>A. Correct.</b></p> <p>2 Q. And there is no evidence, in Mrs. Alonso's</p> <p>3 medical records, that she's had any recurrence of stress</p> <p>4 urinary incontinence, true?</p> <p>5 MS. GAYLE: Objection. Form.</p> <p>6 BY THE WITNESS:</p> <p>7 <b>A. On my discussion with the patient, and I</b></p> <p>8 <b>believe I go over that here. I have to find it as I say</b></p> <p>9 <b>currently. Yeah. Under my exam, as I recall -- here we</b></p> <p>10 <b>go -- she had mild urethral hypermobility with no SUI</b></p> <p>11 <b>noted. However, her bladder was empty at the time of</b></p> <p>12 <b>the examination. So on my exam, on that day, I did not</b></p> <p>13 <b>elicit any urinary incontinence.</b></p> <p>14 Q. And there is nothing in her records reflecting</p> <p>15 any stress urinary incontinence either, true, since --</p> <p>16 <b>A. I --</b></p> <p>17 Q. -- since the implant of the Bard Align</p> <p>18 product?</p> <p>19 <b>A. I do not recall that being a problem that she</b></p> <p>20 <b>had mentioned, no.</b></p> <p>21 Q. So, in other words, the Bard Align sling</p> <p>22 product is doing exactly what it was intended to do,</p> <p>23 treat and resolve the stress urinary incontinence</p> <p>24 problems Mrs. Alonso is experiencing?</p> <p>25 MS. GAYLE: Objection. Form.</p>



In Re: CR Bard 200

Daniel Elliott M.D., Vol. II

11/16/2014

<p style="text-align: right;">Page 605</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A. Yeah, I don't -- I do not recall any mention</b></p> <p>3 <b>regarding stress urinary incontinence.</b></p> <p>4 Q. So, in other words, the product worked? It's</p> <p>5 doing what it was intended to do, correct?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p>8 <b>A. I don't believe anybody is going to challenge</b></p> <p>9 <b>whether or not a product, a given sling product, can</b></p> <p>10 <b>treat stress incontinence. It's the complications from</b></p> <p>11 <b>that sling product which are the issue.</b></p> <p>12 Q. But in her case, Mrs. Alonso's case, we've</p> <p>13 already talked about this extensively, you're</p> <p>14 attributing all of her complications to the Bard Avaulta</p> <p>15 product, the POP product and not the sling product,</p> <p>16 true?</p> <p>17 <b>A. No.</b></p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. No. What I've stated, and we'd need to go</b></p> <p>21 <b>back to exactly what I stated, I'll paraphrase it. The</b></p> <p>22 <b>Avaulta Align -- excuse me, the Align transobturator</b></p> <p>23 <b>sling, which is heavyweight, small pore, goes through</b></p> <p>24 <b>the obturator foramen in essentially the exact location</b></p> <p>25 <b>as the Avaulta mesh.</b></p>	<p style="text-align: right;">Page 607</p> <p>1 you had to eat, so --</p> <p>2 <b>THE WITNESS: And I have a flight at 5:15, which</b></p> <p>3 <b>will take me 25 minutes to get there.</b></p> <p>4 MS. GAYLE: Well, she said that these will be</p> <p>5 shorter, so...</p> <p>6 THE REPORTER: Can we go off?</p> <p>7 MS. GEIST: Yeah. Let's go off the record.</p> <p>8 VIDEO TECHNICIAN: We're off the record. The time</p> <p>9 is 11:53 a.m.</p> <p>10 (A recess was had.)</p> <p>11 VIDEO TECHNICIAN: We're back on the record. The</p> <p>12 time is 12:15 p.m.</p> <p>13 BY MS. GEIST:</p> <p>14 Q. So, Dr. Elliott, we just had a very quick</p> <p>15 lunch break and let's continue on with your opinions in</p> <p>16 the case of Martina Wheeler. Okay?</p> <p>17 <b>A. Okay.</b></p> <p>18 Q. And, Doctor, we've previously marked your</p> <p>19 notice of deposition, and that actually applies to the</p> <p>20 three cases in which you've given a specific report,</p> <p>21 Mrs. Alonso, Mrs. Wheeler, and Mrs. Bolyard. And that's</p> <p>22 Exhibit 28, correct?</p> <p>23 <b>A. Yes. Correct. That is correct.</b></p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 606</p> <p>1 <b>So, on my exam, she has severe pain in that</b></p> <p>2 <b>region and scarring. Statistically speaking, due to the</b></p> <p>3 <b>larger volume of mesh with meaning, you know, the arms</b></p> <p>4 <b>of the Avaulta, statistically speaking, it is more</b></p> <p>5 <b>likely than not to be due to the Avaulta than the Align,</b></p> <p>6 <b>period.</b></p> <p>7 Q. Okay. Doctor, I want to move on to</p> <p>8 Mrs. Wheeler now. Do you want to take a break?</p> <p>9 <b>A. No.</b></p> <p>10 Q. And how about the court reporter?</p> <p>11 <b>A. She's fine. She's happy. She's happy to be</b></p> <p>12 <b>here. Do you need a break?</b></p> <p>13 Q. I think we're all happy to be here, Doctor,</p> <p>14 but I need to just go to the court reporter because she</p> <p>15 has the hardest job of all of us.</p> <p>16 <b>A. She's nodding. She's fine.</b></p> <p>17 Q. She is?</p> <p>18 <b>A. Yes, she went like that. (Indicating.)</b></p> <p>19 Q. I can't tell.</p> <p>20 MS. GAYLE: Lunch?</p> <p>21 <b>THE WITNESS: Do you need a break?</b></p> <p>22 MS. GAYLE: Can we take a short, like maybe ten</p> <p>23 minutes lunch break.</p> <p>24 MS. GEIST: Yes.</p> <p>25 MS. GAYLE: Madame Court Reporter, I know you said</p>	<p style="text-align: right;">Page 608</p> <p>1 (Elliott Deposition Exhibit No. 33</p> <p>2 was marked for identification.)</p> <p>3 BY MS. GEIST:</p> <p>4 Q. And I've marked as Exhibit 33 your</p> <p>5 case-specific report in Mrs. Wheeler's case. And, as</p> <p>6 I -- I'm sorry. As I indicated to you earlier, Doctor,</p> <p>7 I'm not going to ask you the same generally applicable</p> <p>8 questions that we just went through with respect to</p> <p>9 Mrs. Alonso's case. Okay.</p> <p>10 And, with respect to your opinions in</p> <p>11 Mrs. Wheeler's case, is it fair to say that you formed</p> <p>12 your opinions in that case using the same methodology</p> <p>13 that you used in Mrs. Alonso's case?</p> <p>14 <b>A. Correct. As I outlined earlier, it would be</b></p> <p>15 <b>the same process.</b></p> <p>16 Q. Okay?</p> <p>17 MS. GAYLE: Counsel, just for the record, you</p> <p>18 handed me what's Exhibit 33, and that does not have his</p> <p>19 exhibit attachments to that. I just wanted to note that</p> <p>20 for the record.</p> <p>21 MS. GEIST: Thank you. And I was -- I was actually</p> <p>22 going to get to that.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. And your attachments to Mrs. Wheeler's report</p> <p>25 I didn't bring with me separately because they're the</p>

<p style="text-align: right;">Page 609</p> <p>1 same. They have your CV and your materials relied list.</p> <p>2 The only difference would be case-specific materials and</p> <p>3 records relating to Mrs. Wheeler, correct?</p> <p>4 <b>A. Correct, yes.</b></p> <p>5 Q. And you have that in the version that you're</p> <p>6 looking at now?</p> <p>7 <b>A. Yeah. This is my copy highlighted with one</b></p> <p>8 <b>set of notes, but I can just rely off yours. That was</b></p> <p>9 <b>just for efficiency's sake.</b></p> <p>10 Q. Okay. And let's just make sure we're all</p> <p>11 clear that that is a final copy of the report.</p> <p>12 <b>A. Oh.</b></p> <p>13 MS. GAYLE: He's not going to rely -- he's not</p> <p>14 going to look at it.</p> <p>15 <b>THE WITNESS: Yes.</b></p> <p>16 MS. GAYLE: Because I have not taken the time to --</p> <p>17 this one is the final copy that you handed me, your</p> <p>18 Exhibit 33, but I took away from him his earlier copies</p> <p>19 because, honestly, I only did a line-by-line comparison</p> <p>20 of one and found that it's a draft. But for</p> <p>21 efficiency's sake, I just took everything away from him.</p> <p>22 He was just asking if he should highlight for efficiency</p> <p>23 purposes like you allowed him to do earlier, but we're</p> <p>24 good.</p> <p>25 <b>THE WITNESS: And I don't need to. We -- yeah.</b></p>	<p style="text-align: right;">Page 611</p> <p>1 Q. And, just as I did with you, Doctor, with</p> <p>2 Mrs. Alonso, I just want to summarize the opinions you</p> <p>3 have in Mrs. Wheeler's case, okay?</p> <p>4 <b>A. Okay.</b></p> <p>5 Q. So in terms of her symptomatology, in your</p> <p>6 opinion, she experiences pelvic pain, pelvic floor</p> <p>7 myalgia, urge incontinence, dyspareunia, and similarly</p> <p>8 loss of quality of life, which may have a long-term</p> <p>9 impact. Is that a fair summary?</p> <p>10 <b>A. That is correct.</b></p> <p>11 Q. Okay. And, in Mrs. Wheeler's case, she was</p> <p>12 implanted with the Avaulta Solo products to treat both</p> <p>13 an anterior and a posterior defect, correct?</p> <p>14 <b>A. And, yes, she had Avaulta Solo posterior</b></p> <p>15 <b>Avaulta Solo anterior, and an Align TOT for</b></p> <p>16 <b>incontinence.</b></p> <p>17 Q. Similarly, Doctor, in your opinions with</p> <p>18 respect to Mrs. Alonso, you don't have any opinions that</p> <p>19 the Align sling was the predominant cause or substantial</p> <p>20 cause of the complaints that Mrs. Wheeler has; is that</p> <p>21 correct?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. Same as my testimony with Alonso, that, based</b></p> <p>25 <b>upon my experience, statistics, data, available</b></p>
<p style="text-align: right;">Page 610</p> <p>1 <b>We're good with that.</b></p> <p>2 BY MS. GEIST:</p> <p>3 Q. Okay. So with Mrs. Wheeler, in forming your</p> <p>4 opinions with respect to her case, Doctor, did you do a</p> <p>5 differential diagnosis?</p> <p>6 <b>A. Yes. As outlined previously in the Alonso</b></p> <p>7 <b>case, I used the same process, same differential</b></p> <p>8 <b>diagnosis, same consideration, keeping an open mind of</b></p> <p>9 <b>all possibilities.</b></p> <p>10 Q. Okay. And the alternative possibilities or</p> <p>11 medical conditions or causes of the issues complained of</p> <p>12 by Mrs. Wheeler are not specifically set forth in any</p> <p>13 list that I can read in your report in Mrs. Wheeler's</p> <p>14 case, true?</p> <p>15 <b>A. No. It is exactly as outlined in my testimony</b></p> <p>16 <b>on Alonso. The same process, the same options were</b></p> <p>17 <b>considered and ruled out with the exception of with</b></p> <p>18 <b>Wheeler of the Osler-Weber-Rendu syndrome as indicated</b></p> <p>19 <b>in my report on page 2. That would be a unique</b></p> <p>20 <b>diagnosis that Ms. Alonso obviously did not have.</b></p> <p>21 Q. And you considered that in reaching your</p> <p>22 opinion that that did not contribute in any way to</p> <p>23 Mrs. Wheeler's complaints; is that correct?</p> <p>24 <b>A. Correct. I have no logical evidence that that</b></p> <p>25 <b>was playing a role in her outcome.</b></p>	<p style="text-align: right;">Page 612</p> <p>1 <b>manuscripts, and internal documentation, statistically</b></p> <p>2 <b>speaking, the Avaulta Solo anterior would be responsible</b></p> <p>3 <b>for what I found on my exam, much more so than the</b></p> <p>4 <b>Align.</b></p> <p>5 Q. Okay. And just so we're clear, there's no</p> <p>6 opinions with respect to the Bard Align sling product in</p> <p>7 your report for Mrs. Wheeler, correct?</p> <p>8 MS. GAYLE: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A. I do not -- I do not state anything along</b></p> <p>11 <b>those lines in my report.</b></p> <p>12 Q. Okay. And she was implanted with the Avaulta</p> <p>13 and Align products by Dr. Sprock on July 7th, 2008,</p> <p>14 correct?</p> <p>15 <b>A. That is what my records reflect, yes.</b></p> <p>16 Q. And we already discussed that she was</p> <p>17 implanted with the Avaulta Solo products, correct?</p> <p>18 <b>A. Correct. Solo anterior and posterior.</b></p> <p>19 Q. So your opinions with respect to the Avaulta</p> <p>20 Plus products, which are a collagen/polypropylene</p> <p>21 combination product, any of those opinions would not</p> <p>22 apply in Mrs. Wheeler's case; is that fair to say?</p> <p>23 <b>A. With the exception that the arms of the Solo</b></p> <p>24 <b>are the same, high-density, small pore. The issues</b></p> <p>25 <b>pertaining to collagen and the hypersensitivity, et</b></p>

<p style="text-align: right;">Page 613</p> <p><b>1 cetera, do not apply to Mrs. Wheeler.</b></p> <p>2 Q. On -- okay. So, Doctor, let me start by</p> <p>3 asking you whether you considered a number of different</p> <p>4 things with respect to Mrs. Wheeler in reaching your</p> <p>5 differential. Okay?</p> <p>6 <b>A. Okay.</b></p> <p>7 Q. In concluding or opining that the Bard Avaulta</p> <p>8 products were the cause for her dyspareunia and pelvic</p> <p>9 pain, did you consider the fact that Mrs. Wheeler is in</p> <p>10 her mid-50s and menopausal?</p> <p>11 <b>A. Yes. That is always a consideration. The</b></p> <p>12 <b>hormonal status at age 50 -- actually, the hormonal</b></p> <p>13 <b>status is going to be still fairly decent.</b></p> <p>14 Q. Isn't it true, Doctor, that there could be</p> <p>15 significant pain or dyspareunia associated with</p> <p>16 intercourse in a woman whose vagina is atrophic --</p> <p>17 atrophic? Pardon me.</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. Again, we have to put the qualifiers on there.</b></p> <p>21 <b>Atrophic vaginal perimenopausal, post-menopausal can</b></p> <p>22 <b>contribute to vaginal dryness that is usually amenable</b></p> <p>23 <b>to a vaginal lubricant. So it's a different type,</b></p> <p>24 <b>quality, severity of pain.</b></p> <p>25 Q. Well, vaginal atrophy or vaginal thinning due</p>	<p style="text-align: right;">Page 615</p> <p><b>1 high-volume tertiary center, subspecialized in female</b></p> <p><b>2 pelvic medicine, fully board-certified in that, my</b></p> <p><b>3 opinion was she was well-estrogenized.</b></p> <p>4 Q. Excuse me. Are you aware of whether</p> <p>5 Mrs. Wheeler has been taking estrogen therapy for a</p> <p>6 number of years to treat the vaginal atrophy?</p> <p>7 <b>A. I can't recall specifically. Most women have</b></p> <p><b>8 been treated with estrogen from time to time for</b></p> <p><b>9 extrusion. So I would have to see with that.</b></p> <p>10 Q. In reaching your opinion that she experiences</p> <p>11 now severe dyspareunia, did you take into consideration</p> <p>12 her medical records where she reports that her</p> <p>13 dyspareunia is mild?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. Did you see that in any of the medical records</p> <p>17 for Mrs. Wheeler?</p> <p>18 <b>A. Yeah. I've seen various medical records and</b></p> <p><b>19 documentation. All I can speak to specifically is my</b></p> <p><b>20 interaction with her on October 4th where I then used</b></p> <p><b>21 the Visual Analog Pain Scale to be able to compare</b></p> <p><b>22 a rel- -- you can do comparisons that way on severity.</b></p> <p>23 Q. So she -- when she saw you, she told you she</p> <p>24 was experiencing severe dyspareunia; is that right?</p> <p>25 <b>A. She graded her pain using the Visual Analog</b></p>
<p style="text-align: right;">Page 614</p> <p>1 to a woman going through menopause and the correlating</p> <p>2 reduction in estrogen can cause dyspareunia. Do you</p> <p>3 agree with that?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A. That's just what I stated. There would have</b></p> <p><b>7 to be qualifiers on that. That's usually why we use the</b></p> <p><b>8 Visual Analog Pain Scale to determine the severity and</b></p> <p><b>9 the relative severity. She can have dryness. She can</b></p> <p><b>10 have discomfort that is mild and usually treatable with</b></p> <p><b>11 vaginal lubricants.</b></p> <p>12 Q. Did you read and consider Dr. Sprock's, who is</p> <p>13 the implanting physician in the case, her deposition</p> <p>14 where she testified that Mrs. Wheeler has very thin</p> <p>15 tissue and, in fact, an atrophic -- atrophic</p> <p>16 endometrium? Did you consider that in reaching your</p> <p>17 conclusion that the Avaulta products were the cause of</p> <p>18 the dyspareunia?</p> <p>19 <b>A. I would have to look at that specific record</b></p> <p><b>20 with that. However, you said thinned endometrium. I</b></p> <p><b>21 would expect that. She's a perimenopausal,</b></p> <p><b>22 postmenopausal woman. You would expect the uterus to</b></p> <p><b>23 be -- have a thinned endometrium. I can correlate it to</b></p> <p><b>24 my exam on October 4th where I said the vagina was</b></p> <p><b>25 well-estrogenized. So, in my experience, at a</b></p>	<p style="text-align: right;">Page 616</p> <p><b>1 Pain Scale, which is a validated study for patients to</b></p> <p><b>2 be able to compare pain, on a scale of 1 to 10, with 1</b></p> <p><b>3 being essentially nothing, 10 being the most severe pain</b></p> <p><b>4 in life. She graded it at 8 during intercourse.</b></p> <p>5 Q. And did you consider the reliability of that</p> <p>6 grading by Mrs. Wheeler when looking at her medical</p> <p>7 records where she has reported only mild dyspareunia?</p> <p>8 <b>A. Yeah. I am familiar with the records. We</b></p> <p><b>9 probably want to talk -- go look specifically at those</b></p> <p><b>10 notes, when that was, when was it relative to an</b></p> <p><b>11 extrusion and a treatment of extrusion -- extrusion. Is</b></p> <p><b>12 it possibly immediately after the extrusion? The pain</b></p> <p><b>13 might have gone away and then comes back. And,</b></p> <p><b>14 remember, this is also a progressive process.</b></p> <p><b>15 Klosterhalfen, et al., talks about 15 years'</b></p> <p><b>16 progression. So what happened in the past is important,</b></p> <p><b>17 but has to be looked at as the progression of the</b></p> <p><b>18 disease process.</b></p> <p>19 Q. How about Mrs. Wheeler's preimplant complaints</p> <p>20 of trouble with sexual intercourse, specifically burning</p> <p>21 with sexual intercourse. Did you consider those reports</p> <p>22 she made to her doctors in reaching your opinion that it</p> <p>23 was the Bard's product only that has caused her problems</p> <p>24 with sexual intercourse?</p> <p>25 MS. GAYLE: Objection. Form.</p>

<p style="text-align: right;">Page 617</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yeah. Number one, yes, I did consider those.</p> <p>3 Number two, as I stated earlier, as far as the quality</p> <p>4 and severity of the pain. Burning with sexual activity,</p> <p>5 I'm just trying to see if I have a Visual Analog Scale.</p> <p>6 I know I have here somewhere what it was before surgery</p> <p>7 and after surgery. It will be in my note somewhere.</p> <p>8 MS. GAYLE: Take your time, Doctor, and look for</p> <p>9 it.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yeah. I only see in my notes, on quick</p> <p>12 review, a current Visual Analog Scale of 10 with sexual</p> <p>13 activity and a baseline of 6 to 7 constantly. I do not</p> <p>14 see where I state a preoperative Visual Analog Scale. I</p> <p>15 can go off of just what she said as far as advancement</p> <p>16 of the severity.</p> <p>17 Q. That's what she told you, correct?</p> <p>18 A. That's what she told me, yes.</p> <p>19 Q. Did you consider, Doctor, the reasons why</p> <p>20 Mrs. Wheeler's reports of the severity of dyspareunia</p> <p>21 may be different to you compared to her treating doctors</p> <p>22 as reflected in the records?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Every time I interact with an individual I am</p>	<p style="text-align: right;">Page 619</p> <p>1 BY THE WITNESS:</p> <p>2 A. Absolutely I consider it, and that is a very</p> <p>3 important one. And I have to correlate it to my</p> <p>4 experience, my understanding of the medical literature,</p> <p>5 which, again, I have 509 papers that I've reviewed</p> <p>6 regarding this, including documentation on pain. I do</p> <p>7 know that from, again, Klosterhalfen, et al., mesh</p> <p>8 contraction is a progressive process.</p> <p>9 So if an individual has -- does not have pain,</p> <p>10 we have to look at exactly what's going on with that and</p> <p>11 if it progresses. Remember we had the paper yesterday</p> <p>12 where at one year they had 8 percent extrusion and at</p> <p>13 three years they had something like 19 percent, roughly.</p> <p>14 So things change.</p> <p>15 Q. You've mentioned Dr. Klosterhalfen quite a few</p> <p>16 times. Who is he?</p> <p>17 A. Klosterhalfen is a pathologist, Ph.D.,</p> <p>18 specializing in biomaterials. He is considered by some</p> <p>19 to be the king of meshes as far as understanding of</p> <p>20 meshes. And if you look at his CV, he has dozens and</p> <p>21 dozens of papers of looking at animal studies and human</p> <p>22 studies and mesh interaction from the vagina and also</p> <p>23 abdominal wall hernias.</p> <p>24 Q. Do you consider him to be a biomaterials</p> <p>25 expert?</p>
<p style="text-align: right;">Page 618</p> <p>1 always cognizant that people don't always tell the</p> <p>2 truth. You, as lawyers, know that, too. Anybody in the</p> <p>3 legal field knows it, the police force or otherwise. So</p> <p>4 that is always something I consider. All I can go off</p> <p>5 of is my personal interaction. I ask a question, I get</p> <p>6 a response, and then I correlate it to the physical</p> <p>7 exam.</p> <p>8 And when I do a physical exam, being aware of</p> <p>9 what we call malingering, I will try and do an exam,</p> <p>10 distract the patient, touch certain areas that I know</p> <p>11 would not be involved with meshes, ask them, Do you have</p> <p>12 pain here? If a patient is telling me they had pain</p> <p>13 everywhere I touch, inside the thigh, outside the thigh,</p> <p>14 I know that's not due to mesh. So all I can state is my</p> <p>15 questions and my physical exam correlate.</p> <p>16 Q. When you have a case like in any of these</p> <p>17 cases where you have medical records that reflect a much</p> <p>18 lesser degree of dyspareunia, do you consider that at</p> <p>19 all in reaching your opinions that the plaintiff</p> <p>20 experienced severe dyspareunia?</p> <p>21 If the medical record contradicts what she's</p> <p>22 telling you during your exam, do you consider that in</p> <p>23 reaching your conclusion with respect to severe</p> <p>24 dyspareunia?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 620</p> <p>1 A. I consider him to be an advanced level</p> <p>2 individual who understands polymers and their</p> <p>3 interaction with the body.</p> <p>4 Q. So do you consider him to be a biomaterials</p> <p>5 expert?</p> <p>6 MS. GAYLE: Objection. Asked and answered.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Well, I just stated. He has -- he has extreme</p> <p>9 advanced knowledge arguably, the best in the world, in</p> <p>10 understanding meshes and their complications in animal</p> <p>11 and human, vaginal and transabdominal meshes.</p> <p>12 Q. Have you ever met with Dr. Klosterhalfen?</p> <p>13 A. No.</p> <p>14 Q. You read his report in this litigation?</p> <p>15 A. I've read --</p> <p>16 MS. GAYLE: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes. I've read his reports, but I've read</p> <p>19 more so his papers.</p> <p>20 Q. You understand he's an expert for the</p> <p>21 plaintiffs in this litigation as you are, correct?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes. I do understand that, and I also put it</p> <p>25 in the mindset that I read his papers going back to the</p>

<p style="text-align: right;">Page 621</p> <p>1 early '80s, which predate any of this. And what he</p> <p>2 stated then and I correlate to what he states now to see</p> <p>3 if it's changed.</p> <p>4 Q. In reaching your opinions in Mrs. Wheeler's</p> <p>5 case about long-term quality-of-life issues and</p> <p>6 inability to engage in sexual intercourse, did you</p> <p>7 consider Mrs. Wheeler's attitudes or desires to have</p> <p>8 sexual intercourse?</p> <p>9 A. I can't recall exactly what I spoke to her</p> <p>10 about and her motivations as far as sexual activity. I</p> <p>11 stated, you know, based upon my exam and what she stated</p> <p>12 to me, that it's so severe she cannot have sexual</p> <p>13 activity and it's a tremendous impact upon her quality</p> <p>14 of life. So, yes, to answer your question, I did do</p> <p>15 that.</p> <p>16 Q. Well, did you review or see, in any of the</p> <p>17 medical records, Mrs. Wheeler's reports, that she</p> <p>18 couldn't be bothered with sex because they were</p> <p>19 experiencing marital problems?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. Did you see any of that?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I would like to look at those records. The</p>	<p style="text-align: right;">Page 623</p> <p>1 MS. GAYLE: Objection, form. Mischaracterizes</p> <p>2 evidence and testimony in this case.</p> <p>3 BY THE WITNESS:</p> <p>4 A. You're taking a certain -- I would like to see</p> <p>5 those records, which would probably be important. Let's</p> <p>6 see what the context and when it is occurring. However,</p> <p>7 on my interaction with her on October 4th, 2014, what</p> <p>8 she stated to me, which correlates to my physical exam,</p> <p>9 is the impact upon her quality of life has been</p> <p>10 tremendous and cannot engage in any -- cannot. Not that</p> <p>11 she doesn't choose. She cannot engage in significant --</p> <p>12 excuse me, engage in any meaningful -- cannot engage in</p> <p>13 any meaningful sexual activity and has lost that</p> <p>14 intimacy.</p> <p>15 Q. Well, I understand that's what she told you,</p> <p>16 Dr. Elliott. Would Mrs. Wheeler, as a plaintiff in this</p> <p>17 litigation, tell you anything other than that in order</p> <p>18 to move her case forward?</p> <p>19 MS. GAYLE: Objection. Move to strike. Also,</p> <p>20 objection. It mischaracterizes testimony and</p> <p>21 argumentative.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I cannot state what -- what Mrs. Wheeler and</p> <p>24 her various different motivations are. All I can do is</p> <p>25 I ask questions keeping an open mind, keeping the</p>
<p style="text-align: right;">Page 622</p> <p>1 fact that she might not want to be bothered by sexual</p> <p>2 activity is understandable. But then if she were to</p> <p>3 change her mind and not be able to, that is an important</p> <p>4 issue.</p> <p>5 Q. Well --</p> <p>6 A. She should have the right to be able to have</p> <p>7 sexual activity if she chooses to.</p> <p>8 Q. If she has marital problems and she doesn't</p> <p>9 want to be bothered with sex, obviously, she wouldn't</p> <p>10 have any long-term quality-of-life impact, true?</p> <p>11 MS. GAYLE: Object to form. Mischaracterizes</p> <p>12 Ms. Wheeler's testimony and her husband's testimony.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I'm of the opinion the woman should have the</p> <p>15 right to choose what she wants to do with her body. If</p> <p>16 she is having marital discourse or whatever type of</p> <p>17 discourse and does not want to partake in sex, that's</p> <p>18 fine. But if she were to change her mind, she has the</p> <p>19 right to be able to do that.</p> <p>20 Q. And I don't disagree with you. But my</p> <p>21 question only is this, if she's indicated in her medical</p> <p>22 records, maybe not to you, that she couldn't be bothered</p> <p>23 with sex, then obviously she doesn't have any long-term,</p> <p>24 quality-of-life issue if she's not interested in</p> <p>25 engaging in sex? Would you agree with me on that?</p>	<p style="text-align: right;">Page 624</p> <p>1 concept of malingering very well present, correlate it</p> <p>2 to what my physical exam is. And my physical exam</p> <p>3 demonstrated a severely scarred and painful vagina,</p> <p>4 which is not consistent remotely with meaningful sexual</p> <p>5 activity.</p> <p>6 Q. Well, I guess what I'm asking you, Doctor, is</p> <p>7 this, when Mrs. Wheeler reported to you that she's</p> <p>8 experiencing severe dyspareunia, did you go back and</p> <p>9 look at her records and see if that report correlated to</p> <p>10 what she was telling her treating doctors over the</p> <p>11 years?</p> <p>12 A. Well, by all means. I mean, I've read the</p> <p>13 records. But, again, what happened then versus now was</p> <p>14 that, you know, was it when she was having mesh</p> <p>15 extrusion and she wants nothing to do with sexual</p> <p>16 activity? We have to figure out what is exactly going</p> <p>17 on. You're taking one -- one line from somewhere and</p> <p>18 I'm taking, when I examined her and when I personally</p> <p>19 spoke with her, what she said.</p> <p>20 Q. Now, moving to the paragraph regarding the</p> <p>21 lack of physical intimacy and the long-term outcome of</p> <p>22 impact on quality-of-life issues leading to the</p> <p>23 possibility of depression and the suicide, that's the</p> <p>24 same paragraph you have for Mrs. Alonso and Mrs. Wheeler</p> <p>25 and Mrs. Bolyard, correct?</p>



<p style="text-align: right;">Page 625</p> <p>1 <b>A. That is correct.</b></p> <p>2 Q. Okay. So are you giving an opinion in this</p> <p>3 case that Mrs. Wheeler will experience depression or</p> <p>4 commit suicide as a result of the problems that she</p> <p>5 contends she is experiencing?</p> <p>6 <b>A. I stated the same statement as in my previous</b></p> <p>7 <b>testimony with Alonso, that, based upon the data out</b></p> <p>8 <b>there in multiple different manuscripts, my review of</b></p> <p>9 <b>the literature, my daily interaction with female</b></p> <p>10 <b>patients, that the loss of intimacy, the isolation, the</b></p> <p>11 <b>embarrassment, the guilt, the perception of inability</b></p> <p>12 <b>to, for lack of a better phrase, satisfy their partner,</b></p> <p>13 <b>that can lead to depression and all of the emotions we</b></p> <p>14 <b>discuss -- discussed.</b></p> <p>15 Q. It's fair to say it would be speculation to</p> <p>16 opine, in any of these three cases, that any of these</p> <p>17 women will experience depression as a result of the</p> <p>18 complications they say they've had from the mesh?</p> <p>19 MS. GAYLE: Objection. Form.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. It would be speculation to say Mrs. Alonso or</p> <p>22 Mrs. Wheeler or Mrs. Bolyard will experience depression</p> <p>23 based on the complications that they say they've had</p> <p>24 from the Bard mesh?</p> <p>25 MS. GAYLE: Objection. Form. Mischaracterizes</p>	<p style="text-align: right;">Page 627</p> <p>1 Bard implant surgery?</p> <p>2 <b>A. Absolutely. And that's all the more worrisome</b></p> <p>3 <b>in an individual with underlying baseline depression.</b></p> <p>4 <b>Now you have added on another stressor like chronic pain</b></p> <p>5 <b>and then more isolation and more loneliness. So, yes,</b></p> <p>6 <b>that is further evidence or worrisome that, you know,</b></p> <p>7 <b>this is a major, serious tragic problem for these</b></p> <p>8 <b>individuals.</b></p> <p>9 Q. Would you agree with me that Mrs. Wheeler</p> <p>10 could have still experienced depression and would still</p> <p>11 be a user of antidepressants if she never even had the</p> <p>12 Bard implant surgery?</p> <p>13 <b>A. Depression is, unfortunately, frequently not a</b></p> <p>14 <b>curable problem; and, if you add in more stressors, it</b></p> <p>15 <b>makes it worse. So, yes, by all means, depression was</b></p> <p>16 <b>there. That means, again, the more importance of the</b></p> <p>17 <b>added stress of the pain.</b></p> <p>18 Q. Well, you would agree with me, Doctor, that</p> <p>19 you can't say in this circumstance that, if Mrs. Wheeler</p> <p>20 continues to experience depression, that it's all due to</p> <p>21 the problems she says she's had from the Bard surgery --</p> <p>22 from the Bard implant surgery? Pardon me.</p> <p>23 <b>A. That's -- well, again, my report states what</b></p> <p>24 <b>it states. I am not stating that Bard product caused</b></p> <p>25 <b>her original depression. I am saying that -- and I</b></p>
<p style="text-align: right;">Page 626</p> <p>1 testimony and his report. The report speaks for itself.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. Yeah. My report, the words that I wrote down</b></p> <p>4 <b>here, I chose very carefully. I did not state it will</b></p> <p>5 <b>lead to. The symptoms that she is experiencing, based</b></p> <p>6 <b>upon my experience, review of the literature, can lead</b></p> <p>7 <b>to these feelings of isolation, loneliness, depression,</b></p> <p>8 <b>and, unfortunately, suicide.</b></p> <p>9 Q. Well, would you agree with me, Doctor, that</p> <p>10 the use of the term suicide is a pretty highly charged</p> <p>11 term? It's a pretty serious term to throw in there in</p> <p>12 this report?</p> <p>13 <b>A. The data backs it up, though. Look, I had two</b></p> <p>14 <b>quotes there, two papers. And so, yeah, chronic pain,</b></p> <p>15 <b>loss of intimacy, loneliness, depression, I don't think</b></p> <p>16 <b>there is anybody going to challenge that depression and</b></p> <p>17 <b>suicide correlate. I'm not saying they will have it.</b></p> <p>18 <b>I'm saying that these are things that can, in the very</b></p> <p>19 <b>severe situations, lead to that.</b></p> <p>20 Q. How about in Mrs. Wheeler's specific case?</p> <p>21 Did you consider, in reaching your opinions, that the</p> <p>22 quality of life issues that you say were caused by the</p> <p>23 Bard Avaulta products may cause her depression? Did you</p> <p>24 consider, in reaching those opinions, that she had been</p> <p>25 using antidepressants for a number of years prior to the</p>	<p style="text-align: right;">Page 628</p> <p>1 <b>don't think there is anybody who is going to be</b></p> <p>2 <b>questioning this -- that added stress, pain, loneliness,</b></p> <p>3 <b>lack of intimacy can worsen the condition.</b></p> <p>4 Q. I assume you would agree with me, Doctor, that</p> <p>5 you're not an expert in psychiatry or psychology, true?</p> <p>6 <b>A. I am not trained in psychology or psychiatry.</b></p> <p>7 Q. So you're not an expert in either of those</p> <p>8 fields, correct? You wouldn't hold yourself out as an</p> <p>9 expert in the fields of psychiatry or psychology or</p> <p>10 mental health, in general?</p> <p>11 <b>A. No. Those, I think every physician deals with</b></p> <p>12 <b>individuals dealing with major issues. To a certain</b></p> <p>13 <b>extent, every physician, especially if they deal with</b></p> <p>14 <b>pain, has to be aware and recognize these and also aware</b></p> <p>15 <b>and recognize their limitations to ask certain questions</b></p> <p>16 <b>and get the individual to somebody with advanced</b></p> <p>17 <b>training.</b></p> <p>18 Q. Doctor, I'm asking if you recognize your</p> <p>19 limitations. Are you putting yourself out there as an</p> <p>20 expert in psychiatry, psychology, and mental health</p> <p>21 disorders?</p> <p>22 MS. GAYLE: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. Well, no. I think I answered that. No, I am</b></p> <p>25 <b>not a psychiatrist or a psychologist, but I deal with a</b></p>

<p style="text-align: right;">Page 629</p> <p>1 large number of women who suffer from depression and</p> <p>2 things, but I do not hold myself out as being an expert</p> <p>3 in psychology or psychiatry. I do not hold an advanced</p> <p>4 degree in that area.</p> <p>5 Q. Okay. Thank you. Did you see, in your review</p> <p>6 of Mrs. Wheeler's records, that she experienced a</p> <p>7 dehiscence in weeks postop?</p> <p>8 A. Yeah. Her surgery was on July 7th, 2008. And</p> <p>9 on August 26th -- August 26th is when it was clear.</p> <p>10 But, though, if you go back to July 22nd, I think we</p> <p>11 start to see the beginnings of the dehiscence, that it</p> <p>12 manifested itself on August 26th.</p> <p>13 Q. And just so the jury understands, a dehiscence</p> <p>14 is what?</p> <p>15 A. It's a separation of a wound, poor healing.</p> <p>16 Q. It's sort of a wound rupture at the suture</p> <p>17 site; is that correct?</p> <p>18 A. Yeah. Well, dehiscence technically just means</p> <p>19 a separation. In a surgical setting, it is implied that</p> <p>20 that is the incision that opens.</p> <p>21 Q. And, in this case, the separation we're</p> <p>22 talking about is the vaginal wall, correct?</p> <p>23 A. The -- correct. The anterior, 4-millimeter</p> <p>24 mesh extrusion on August 26th. So it is just the</p> <p>25 anterior component. According to Dr. Sprock's note,</p>	<p style="text-align: right;">Page 631</p> <p>1 A. No. The surgery was July 7th. July 22nd she</p> <p>2 was examined. The tissue was turned a little yellowish.</p> <p>3 Now, Dr. Sprock says it's part of the healing process.</p> <p>4 What I'm saying is, in hindsight -- I don't disagree</p> <p>5 with Dr. Sprock at that moment; but, in hindsight, that</p> <p>6 was probably the start of impaired healing.</p> <p>7 Q. So two weeks out from the surgery, the</p> <p>8 dehiscence had started, correct?</p> <p>9 A. No. I'm saying, if we want to go purely off</p> <p>10 of the record, Dr. Sprock states it's part of the</p> <p>11 healing process. So she was there. She laid eyes on</p> <p>12 the individual. I did not. So if we go off of her</p> <p>13 record, she's saying this is normal healing. So then</p> <p>14 the 26th, clear-cut that there is impaired healing and</p> <p>15 the dehiscence.</p> <p>16 Q. Now, Dr. Sprock did not repair the dehiscence</p> <p>17 when she made that diagnosis in her patient,</p> <p>18 Mrs. Wheeler, correct?</p> <p>19 A. No. It says, on the August 26th office visit,</p> <p>20 she noticed an anterior 4-millimeter mesh extrusion.</p> <p>21 Mesh is our word we put in there. Dr. Sprock trimmed</p> <p>22 the extrusion and sutured the site closed. So she did</p> <p>23 repair it.</p> <p>24 Q. Did you review the record for Mrs. Wheeler on</p> <p>25 September 23rd, 2008, when wound dehiscence was noted as</p>
<p style="text-align: right;">Page 630</p> <p>1 there was -- well, actually, I have nothing down here</p> <p>2 pertaining to posterior. So it was just anterior.</p> <p>3 Q. The dehiscence or the separation of the</p> <p>4 vaginal wall would cause the exposure of the mesh,</p> <p>5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. And what are some of the known causes of</p> <p>8 dehiscence in the first instance?</p> <p>9 A. Implantation of mesh, surgery, wound</p> <p>10 infection. You know, those are probably the top things</p> <p>11 that come to my mind.</p> <p>12 Q. Is surgical error one of the known causes for</p> <p>13 wound dehiscence?</p> <p>14 A. Not eight weeks out, ten weeks out.</p> <p>15 Immediately after surgery, if a wound breaks open, and</p> <p>16 I'd be willing to go on -- obviously, I am on the</p> <p>17 record. If a wound breaks open a day or two after</p> <p>18 surgery, unless you have a hematoma, that would probably</p> <p>19 be poor surgical technique.</p> <p>20 Q. Well --</p> <p>21 A. Closing at ten weeks afterwards, then you</p> <p>22 start talking about poor healing.</p> <p>23 Q. Well, you actually corrected me and you said</p> <p>24 the dehiscence started earlier, that it started in July</p> <p>25 of 2008?</p>	<p style="text-align: right;">Page 632</p> <p>1 well as the extrusion and it was also noted that the</p> <p>2 patient does not desire surgical suturing?</p> <p>3 A. Yeah. Again, I have that note down here from</p> <p>4 the 23rd. I would have to review the exact records.</p> <p>5 But, according to my note -- oh, excuse me. You're</p> <p>6 correct. You said September 23rd, patient aware of</p> <p>7 dehiscence, not bothered with intercourse, and left it.</p> <p>8 But then it was then repaired on October 10th. But you</p> <p>9 are correct, on the September 23rd, no repair was done.</p> <p>10 Q. So you think the October which date now?</p> <p>11 A. September 23rd, 2008, eight-week visit,</p> <p>12 Dr. Sprock again noticed vaginal mesh extrusion.</p> <p>13 According to my notes, and we can correlate that with</p> <p>14 the records, at that point in time, no treatment was</p> <p>15 done. However, on October 10th, so, roughly, what,</p> <p>16 two -- two and a half weeks later, Ms. Wheeler returned,</p> <p>17 the mesh extrusion was, again, noted and then it was cut</p> <p>18 and they continued conservative therapy from then.</p> <p>19 Q. Now, the October 10th, 2008 record notes the</p> <p>20 extrusion, as you've just said, and that the extrusion</p> <p>21 was cut or there was an excision done?</p> <p>22 A. Correct.</p> <p>23 Q. Is there any record that notes that the</p> <p>24 dehiscence was repaired?</p> <p>25 A. Well, no. They -- you wouldn't necessarily be</p>

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<p style="text-align: right;">Page 633</p> <p>1 suturing that up at that point in time.</p> <p>2 Q. Why not?</p> <p>3 A. Because it won't heal. It's infected. It's</p> <p>4 contaminated tissue. If you close it over, you're more</p> <p>5 likely to create an abscess. So the standard treatment</p> <p>6 that far out would be just to excise the mesh. Get rid</p> <p>7 of the foreign body back as far as you can with the hope</p> <p>8 the tissue is going to granulate in.</p> <p>9 Q. So is it your opinion that it was within the</p> <p>10 standard of care not to repair the wound dehiscence?</p> <p>11 A. I -- on which day are we talking about,</p> <p>12 October 10th?</p> <p>13 Q. Right.</p> <p>14 A. Okay.</p> <p>15 Q. Is that the ten-week follow-up postop visit?</p> <p>16 A. That is ten-and-a-half-week follow-up, yes.</p> <p>17 The ten and a half weeks out I would not have closed a</p> <p>18 mesh extrusion. I would have trimmed the mesh either in</p> <p>19 the clinic setting or in the operating room, but I would</p> <p>20 not have closed the wound.</p> <p>21 Q. If Mrs. Wheeler had engaged in sexual activity</p> <p>22 after that time, could that have led to some</p> <p>23 complications relating to the mesh due to the wound</p> <p>24 dehiscence?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 635</p> <p>1 advise a woman to refrain from engaging in sexual</p> <p>2 intercourse when she has a vaginal wound dehiscence?</p> <p>3 A. Well, at 26 -- August 26th, it's a</p> <p>4 4-millimeter mesh extrusion, okay, which is, what, not</p> <p>5 even a quarter of an inch. Maybe less than that. Let</p> <p>6 me just find out what that would be at. 4 millimeters</p> <p>7 is, at the most, a quarter of an inch. Dr. Sprock did</p> <p>8 the appropriate thing. She closed it, trimmed the mesh,</p> <p>9 and then closed it. And I don't know when she started</p> <p>10 sexual activity. But -- again, there's certain gaps</p> <p>11 here. I think we have to look at the deposition and</p> <p>12 talk to Dr. Sprock and the patient.</p> <p>13 Q. Sitting here today, you can't tell me one way</p> <p>14 or the other whether it would be within the standard of</p> <p>15 care to instruct a woman experiencing vaginal wound</p> <p>16 dehiscence to avoid sexual intercourse?</p> <p>17 MS. GAYLE: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Well, I think that's actually a very good</p> <p>20 thing for the IFU to help out the physician. I don't</p> <p>21 know of a standard out there with meshes of what to do.</p> <p>22 I don't know of any paper out there. If a company has</p> <p>23 information that, if there is a wound dehiscence and</p> <p>24 delayed healing, completely avoid anything per vagina</p> <p>25 would actually be very helpful. That would be an</p>
<p style="text-align: right;">Page 634</p> <p>1 BY THE WITNESS:</p> <p>2 A. After October 10th?</p> <p>3 Q. Yes.</p> <p>4 A. Well, I don't know. I would have to see the</p> <p>5 record as far as if there are warnings about not</p> <p>6 becoming sexually active, but I can't speak to that.</p> <p>7 Q. Well, if there's no warnings in the records</p> <p>8 for Mrs. Wheeler about not becoming sexually active, is</p> <p>9 it your opinion that she should have been told not to</p> <p>10 become sexually active with a wound dehiscence?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, I would have to look at -- I just say,</p> <p>14 in my notes, going off Dr. Sprock's note, it says a mesh</p> <p>15 extrusion was noted. I don't have the dimensions of</p> <p>16 that extrusion. If the extrusion were large</p> <p>17 centimeters, then I think abstaining from sexual</p> <p>18 activity is appropriate.</p> <p>19 If it's just the prongs poking through and</p> <p>20 it's a minimal deal, then there's probably minimal</p> <p>21 warning that needs to be given to the patient. So,</p> <p>22 again, I don't know -- or, unfortunately, our notes are</p> <p>23 not clear as far as the degree of extrusion.</p> <p>24 Q. Well, what about the wound dehiscence,</p> <p>25 specifically? Isn't it standard of care to instruct or</p>	<p style="text-align: right;">Page 636</p> <p>1 instruction that probably could have helped Dr. Sprock</p> <p>2 if you feel that she did something inappropriate. I</p> <p>3 don't -- again, I don't know. I can't say. I can't</p> <p>4 throw fault here.</p> <p>5 Q. You don't have an opinion one way or the</p> <p>6 other; is that fair to say?</p> <p>7 MS. GAYLE: Objection, form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Well, no. I did say. I said that she,</p> <p>10 Dr. Sprock, is the one who we say laid eyes on the</p> <p>11 patient, did the exam. I don't know what warnings she</p> <p>12 gave. So there is nothing clear in the literature.</p> <p>13 There is nothing in the IFU to say, Hey, if you've got a</p> <p>14 complication, be careful with this.</p> <p>15 Q. Did -- in reaching your opinions in</p> <p>16 Mrs. Wheeler's case that the mesh was the cause or is</p> <p>17 the cause of her reported symptoms, did you consider</p> <p>18 surgical technique?</p> <p>19 A. Oh, I -- I'm sorry. Absolutely. Every time I</p> <p>20 review a patient, as I've stated previously with Alonso,</p> <p>21 we're looking at the totality of that patient, their</p> <p>22 medical records, their past medical history, all of the</p> <p>23 diagnoses, the surgical implementation, the management</p> <p>24 of this patient after surgery.</p> <p>25 Q. Did you consider whether Dr. Sprock implanted</p>

<p style="text-align: right;">Page 637</p> <p>1 the mesh too tight and not tension-free on July 7th, 2 2008?</p> <p>3 MS. GAYLE: Objection. Form.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. I would have to go back to the operative note</b> 6 <b>to go over that specifically, which I don't have. In</b> 7 <b>reading the notes, on all of the individuals today, I</b> 8 <b>cannot point to something that I could say would be a</b> 9 <b>medical error or malpractice. It would all have been</b> 10 <b>within acceptable surgical standards.</b></p> <p>11 Q. Did you read the testimony from Dr. Zipper in 12 Mrs. Wheeler's case?</p> <p>13 <b>A. Yeah. Dr. Zipper? Yes. Yes. Dr. Zipper is</b> 14 <b>in her -- I believe in Dr. Sprock's group, former group.</b> 15 <b>And according to my recollection -- and I could be</b> 16 <b>wrong. We could pull out that actual deposition -- he</b> 17 <b>stated that she did not do anything surgically</b> 18 <b>incorrect.</b></p> <p>19 Q. Do you recall Dr. Zipper testifying that, when 20 he examined Mrs. Wheeler, that the mesh arms were too 21 tight and that this was possibly contributing to her 22 dyspareunia?</p> <p>23 <b>A. I do not recall that specific deposition. We</b> 24 <b>can look at it. However, I would agree completely with</b> 25 <b>that diagnosis. These mesh arms, as I've stated, are</b></p>	<p style="text-align: right;">Page 639</p> <p>1 <b>A. That is correct.</b></p> <p>2 Q. The language that I pointed you to earlier on 3 the IFU for the Avaulta Plus product where it says that 4 the mesh should be implanted tension-free, that's the 5 same language in the Avaulta Solo IFU; is it not?</p> <p>6 <b>A. My recollection, we'd have to compare them</b> 7 <b>side by side, as they are essentially the same document.</b> 8 <b>But I would not agree with you as far as it being</b> 9 <b>tension-free. They mentioned twice avoid excessive</b> 10 <b>tension, without excessive tension.</b></p> <p>11 Q. Now, we looked at the operative note in 12 Mrs. Alonso's case, correct?</p> <p>13 <b>A. That is correct.</b></p> <p>14 Q. And you would agree with me that, when we 15 looked at that operative note, that medical record, 16 nowhere in it did it indicate that the mesh was placed 17 tension-free?</p> <p>18 <b>A. No. But I would say it is stated it avoided</b> 19 <b>excessive pressure. He said apply positive pressure</b> 20 <b>against the posterior bladder. That, to me, is not</b> 21 <b>excessive tension.</b></p> <p>22 Q. But it doesn't say, I avoided excess tension 23 or I placed the mesh tension-free? It doesn't say that 24 in the operative report for Mrs. Alonso, does it?</p> <p>25 MS. GAYLE: Objection. Form. He's asked and</p>
<p style="text-align: right;">Page 638</p> <p>1 <b>high-density, small pore. They contract over time. So,</b> 2 <b>by all means, they're tight. Based upon my exam on</b> 3 <b>October 4th, I felt that knot -- I forget which side --</b> 4 <b>extremely painful in the obturator foramen. So I agree.</b> 5 <b>They are too tight.</b></p> <p>6 Q. But did you consider the possibility that the 7 arms of the mesh were too tight because Dr. Sprock's 8 surgical technique was not according to the IFU as we 9 looked at earlier together?</p> <p>10 <b>A. We would have to pull out the actual operative</b> 11 <b>note. From my recollection, from all individuals, that</b> 12 <b>this is put in loose with avoiding excessive tension as</b> 13 <b>what the IFU specifically states. I do not recall</b> 14 <b>anything, from this operative note, stating anything</b> 15 <b>about it being excessively tight.</b></p> <p>16 MS. GAYLE: And, just for the record, Elliot 30 is 17 the Avaulta Plus IFU, and this is an Avaulta Solo 18 product, and your question referenced the IFU that we 19 looked at earlier, which is the Plus.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. Point well taken by counsel. But, Doctor, you 22 looked at the IFUs for the Plus product and the Solo 23 product, correct --</p> <p>24 <b>A. That is correct.</b></p> <p>25 Q. -- on your reliance list?</p>	<p style="text-align: right;">Page 640</p> <p>1 answered that question previously, and I thought we were 2 on to Wheeler.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. He does not use those exact words; however, I</b> 5 <b>do feel he is following the specific words of the IFU</b> 6 <b>saying avoid excessive tension. He is avoiding</b> 7 <b>excessive tension, so he is following the IFU.</b></p> <p>8 Q. That's your interpretation of the report in 9 Mrs. Alonso's case?</p> <p>10 <b>A. As a surgeon who takes care of these with a</b> 11 <b>large amount of experience, yes. He is following --</b> 12 <b>this is not just an opinion. He is following the</b> 13 <b>avoiding excessive tension, which is mentioned twice in</b> 14 <b>the IFU.</b></p> <p>15 Q. And what about Dr. Sprock? Did Dr. Sprock 16 similarly avoid implanting the Avaulta Solo products in 17 Mrs. Wheeler?</p> <p>18 <b>A. I would have to see that operative note.</b></p> <p>19 Q. You don't remember one way or the other 20 sitting here today?</p> <p>21 <b>A. I read a lot of operative notes and I'd want</b> 22 <b>to -- because this is very important to know the tension</b> 23 <b>of this. I would want to see the exact operative note.</b></p> <p>24 MS. GEIST: Can we go off the record one minute?</p> <p>25 VIDEO TECHNICIAN: We're off the record. The time</p>



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<p style="text-align: right;">Page 641</p> <p>1 is 12:59 p.m.</p> <p>2 (A short recess was had.)</p> <p>3 VIDEO TECHNICIAN: We're back on the record. The</p> <p>4 time is 1:01 p.m.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. Dr. Elliott, as you requested, you wanted to</p> <p>7 see the operative note for Mrs. Wheeler, Mrs. Wheeler's</p> <p>8 procedure?</p> <p>9 <b>A. Correct.</b></p> <p>10 Q. So that was in the materials you had reviewed</p> <p>11 in forming your opinions about Mrs. Wheeler's case,</p> <p>12 correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 MS. GEIST: I think I'm up to Exhibit 32.</p> <p>15 THE REPORTER: 34.</p> <p>16 (Elliott Deposition Exhibit No. 34</p> <p>17 was marked for identification.)</p> <p>18 BY MS. GEIST:</p> <p>19 Q. 34, thank you. Doctor, let me hand you what</p> <p>20 we've marked as Exhibit 34. I apologize for the fact</p> <p>21 that it doesn't have staples.</p> <p>22 MS. GAYLE: I'm going to take care of that for you,</p> <p>23 Counsel.</p> <p>24 MS. GEIST: Thank you, ma'am.</p> <p>25 MS. GAYLE: I travel with a stapler.</p>	<p style="text-align: right;">Page 643</p> <p>1 (Record read as requested.)</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. It states here, tensed with an 8 Hegar</b></p> <p>4 <b>dilator. So that means an 8 Hegar dilator was able to</b></p> <p>5 <b>be inserted between the mesh. So that means it was</b></p> <p>6 <b>placed loosely.</b></p> <p>7 Q. And you are referring to page 2 of the</p> <p>8 operative report, which we just marked as Exhibit 34?</p> <p>9 <b>A. That's correct, on Ms. Wheeler.</b></p> <p>10 Q. And this is the second paragraph,</p> <p>11 second-to-the-last sentence of that paragraph?</p> <p>12 <b>A. Correct.</b></p> <p>13 Q. And that's the basis for your opinion that</p> <p>14 Dr. Sprock implanted the mesh tension-free, that</p> <p>15 sentence that says tensed with an 8 --</p> <p>16 <b>A. Hegar dilator.</b></p> <p>17 Q. -- Hegar dilator?</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. Well, that's --</b></p> <p>21 Q. That's my question.</p> <p>22 <b>A. That's what that means. That means you can</b></p> <p>23 <b>fit an 8 Hegar dilator between the mesh and the tissues.</b></p> <p>24 Q. So that's the basis of your opinion, that the</p> <p>25 mesh was implanted tension-free by Dr. Sprock?</p>
<p style="text-align: right;">Page 642</p> <p>1 MS. GEIST: Thank you, ma'am. I used to. I should</p> <p>2 bring that again.</p> <p>3 BY MS. GEIST:</p> <p>4 Q. I should have just marked the records in the</p> <p>5 entirety, but let's just isolate the operative report</p> <p>6 for Mrs. Wheeler. And this is dated July 7, 2008. Do</p> <p>7 you see that, Doctor?</p> <p>8 <b>A. Correct.</b></p> <p>9 Q. And this is the operative report from</p> <p>10 Dr. Sprock. And you looked at this in the past, I</p> <p>11 assume, in order to inform your opinions in the case?</p> <p>12 <b>A. That is correct.</b></p> <p>13 Q. Okay. Could you tell, from reviewing the</p> <p>14 operative report, whether the implanting surgeon did, in</p> <p>15 fact, place the mesh tension-free?</p> <p>16 MS. GAYLE: Objection. Give him just one moment,</p> <p>17 Counsel, to review this three-page document.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. There's actually nothing on the third page.</p> <p>20 But, Doctor, you can take as much time as you want.</p> <p>21 MS. GAYLE: Sorry.</p> <p>22 BY THE WITNESS:</p> <p>23 <b>A. Okay. I'm done -- I'm done with it. What was</b></p> <p>24 <b>your question again?</b></p> <p>25 MS. GEIST: Can you read back my question, please?</p>	<p style="text-align: right;">Page 644</p> <p>1 MS. GAYLE: Objection. Form.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. Well, that's what - that's what Dr. Sprock</b></p> <p>4 <b>states right here.</b></p> <p>5 Q. I understand that. But is that the basis for</p> <p>6 your opinion that Dr. Sprock implanted the mesh</p> <p>7 tension-free, that sentence?</p> <p>8 MS. GAYLE: Same objection.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A. Yes. That's the basis for my opinion.</b></p> <p>11 Q. Okay. Thank you. You can set that aside,</p> <p>12 Doctor.</p> <p>13 Do you recall, from your review of the records</p> <p>14 in this case, that Dr. Zipper described the mesh as</p> <p>15 being rolled up when that doctor performed an excision</p> <p>16 about four years after the implant?</p> <p>17 <b>A. Yeah. I recall that terminology. And it also</b></p> <p>18 <b>should be noted that Dr. Sprock tacked the mesh anterior</b></p> <p>19 <b>and posterior, so following the IFU instructions.</b></p> <p>20 Q. If the mesh had been implanted flat and</p> <p>21 without tension at the time of the initial surgery,</p> <p>22 would it have been possible to see rolling four years</p> <p>23 later due to tissue, due to tissue ingrowth?</p> <p>24 MS. GAYLE: Objection to form.</p> <p>25 BY THE WITNESS:</p>



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<p style="text-align: right;">Page 645</p> <p>1     <b>A. Absolutely. That's mesh contraction. That's</b>  2     <b>what I see on a daily basis.</b>  3     Q. But, Doctor, would you agree with me that,  4     once tissue ingrowth occurs, you are less likely to see  5     erosion for the logical reason that the mesh has ingrown  6     or combined with the woman's tissue; isn't that true?  7     MS. GAYLE: Objection to form.  8     BY THE WITNESS:  9     <b>A. No, it's absolutely wrong.</b>  10    Q. Why?  11    <b>A. That's why we see mesh extrusion years after</b>  12    <b>the implantation and it's a progressive process. As the</b>  13    <b>mesh contracts up to 80 percent, based upon certain</b>  14    <b>studies, there is rolling, folding, uneven pressure on</b>  15    <b>the tissues, especially with the arms. There's uneven</b>  16    <b>pulling on the vagina and extrusion happens because of</b>  17    <b>pressure, poor healing, degradation of the product.</b>  18    Q. What -- what's the basis for your opinion that  19    we see 80 percent of mesh contraction?  20    MS. GAYLE: Objection. Form. I'm sorry. I  21    believe that was a yesterday opinion, but I may have  22    missed it. Did he just mention 80 percent? Madam Court  23    Reporter, can you read back his answer? I'm so sorry,  24    Madam Court Reporter.  25</p>	<p style="text-align: right;">Page 647</p> <p>1     <b>80 percent, I was -- I actually underestimated. It says</b>  2     <b>85 percent here.</b>  3     Q. And was that study an animal study or a study  4     of -- looking at mesh in women?  5     <b>A. Pelvic mesh volumes using translabial</b>  6     <b>ultrasonography that's in females, humans.</b>  7     Q. And we talked yesterday -- and I don't want to  8     repeat it, but just to confirm -- you had not considered  9     the Dietz study in reaching your opinions about mesh  10    contraction, correct?  11    MS. GAYLE: Objection to form. And that is exactly  12    correct, Counsel. It was discussed yesterday. So I'm  13    going to instruct him not to answer that.  14    MS. GEIST: That's fine. He answered it yesterday.  15    BY MS. GEIST:  16    Q. Okay. Doctor, with respect to the opinions in  17    your report, excuse me, from Mrs. Wheeler that go to the  18    risks that you contend Bard should have included in the  19    IFU and did not?  20    <b>A. Correct.</b>  21    Q. That's -- I just want to make sure that we're  22    clear on the record. That's the same list,  23    two-and-a-half page list, that you had in Mrs. Alonso's  24    report, correct?  25    <b>A. It should be the same, yes.</b></p>
<p style="text-align: right;">Page 646</p> <p>1             (Record read as requested.)  2     MS. GAYLE: Excuse me, Counsel. My apologies.  3     Thank you.  4     MS. GEIST: No problem.  5     MS. GAYLE: Please, continue.  6     BY THE WITNESS:  7     <b>A. Okay. Now, what was your question then?</b>  8     Q. I just want to know what studies are you  9     relying on in support of your opinion that we see mesh  10    contraction up to 80 percent?  11    <b>A. I'm relying upon -- I'm going to have to pull</b>  12    <b>out my expert report from yesterday, the general</b>  13    <b>specific. And the section on mesh contraction, I can go</b>  14    <b>through the studies and list them for you.</b>  15    Q. I just want to know the 80 percent one,  16    Doctor?  17    <b>A. Okay. Letouzey, this is on page 19 of my</b>  18    <b>expert report, Letouzey, L-E-T-O-U-Z-E-Y, which I</b>  19    <b>mentioned earlier today, reviewed the long-term</b>  20    <b>placement of mesh, pelvic mesh volumes over time using</b>  21    <b>three-dimensional, translabial ultrasound and found</b>  22    <b>contraction of 30 percent, 65 percent, 85 percent at a</b>  23    <b>follow-up duration of three, six, and eight years.</b>  24    <b>Correlating this with Bard's own internal documents that</b>  25    <b>showed a substantial risk of up to 50 percent. But my</b></p>	<p style="text-align: right;">Page 648</p> <p>1     Q. And it's the same list that you have in  2     Mrs. Bolyard's report?  3     <b>A. That is correct.</b>  4     Q. And would you agree with me, Dr. Elliott, that  5     you can't state, to a reasonable degree of medical  6     certainty or probability, that had all of this  7     information been included by Bard in the IFU for the  8     Avaulta Solo product, that this information would have  9     been conveyed to Mrs. Wheeler by her implanting doctor?  10    MS. GAYLE: Objection. Form.  11    BY THE WITNESS:  12    <b>A. You're forcing me to speculate what another</b>  13    <b>individual would have done.</b>  14    Q. No, no, no. I'm not. I'm asking you not to.  15    I'm asking you to agree with me that you can't say,  16    sitting here today, that had Bard put all of this  17    information in the IFU that you say Bard should have  18    done because Bard knew about all of these risks and  19    didn't communicate them to doctors, if Bard had done  20    what you say Bard should have done, that that  21    information would have been relayed to Mrs. Wheeler?  22    MS. GAYLE: Objection. Form.  23    BY THE WITNESS:  24    <b>A. It should be the decision and moral obligation</b>  25    <b>of the implanting surgeon to have all information</b></p>

<p style="text-align: right;">Page 649</p> <p>1 available. A reasonable surgeon and doctor would relay</p> <p>2 that information on to the patient. I cannot speculate</p> <p>3 what this hypothetical individual would have done had</p> <p>4 they had this information.</p> <p>5 Q. Well, we're not talking about a hypothetical</p> <p>6 individual. We're talking about Dr. Sprock in</p> <p>7 Mrs. Wheeler's case. So that's my question. You</p> <p>8 can't -- you're not going to sit here and say that your</p> <p>9 opinion is had Bard provided all of this information to</p> <p>10 Dr. Sprock in the IFU for the Avaulta Solo product, that</p> <p>11 that information would have been relayed by the doctor</p> <p>12 to his patient, Mrs. Wheeler. You can't say that,</p> <p>13 correct?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. I can state exactly how I stated with Alonso</p> <p>17 and exactly what I'll state with Bolyard, and that I can</p> <p>18 state that a reasonable surgeon would relay that</p> <p>19 information on. I would do it and do it in my practice</p> <p>20 of all known potential complications.</p> <p>21 Q. And you have no way of saying, because it</p> <p>22 would be pure speculation, to use your own words, what</p> <p>23 would have happened in the case of Mrs. Alonso,</p> <p>24 Mrs. Wheeler, and Mrs. Bolyard, correct?</p> <p>25 A. Well, you're asking me to speculate. I can't</p>	<p style="text-align: right;">Page 651</p> <p>1 A. Yeah, you did. You said native repair and</p> <p>2 anterior sacrocolpopexy.</p> <p>3 Q. No. I asked you about -- well, I don't want</p> <p>4 to argue it.</p> <p>5 A. You said same complications.</p> <p>6 Q. No. I said pain and dyspareunia. So let me</p> <p>7 make sure you understand my question, because that's</p> <p>8 always important in these depositions.</p> <p>9 I'm asking you about her complaints of pain</p> <p>10 and dyspareunia. And my question is this, had she had a</p> <p>11 native tissue repair or an abdominal sacrocolpopexy,</p> <p>12 instead of a transvaginal mesh procedure, could she</p> <p>13 still have experienced pain and dyspareunia after either</p> <p>14 one of those other procedures?</p> <p>15 MS. GAYLE: Objection. Form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Not in my practice, my experience, at a</p> <p>18 high-volume tertiary care center, taking care of</p> <p>19 patients on a daily basis. I have never seen a native</p> <p>20 repair or an abdominal sacrocolpopexy or robotic</p> <p>21 sacrocolpopexy with the severity of pain and the</p> <p>22 location of the pain and the delayed onset of pain like</p> <p>23 I've seen with pelvic meshes. The same answer I gave</p> <p>24 with Alonso and the same one I'll give with Bolyard.</p> <p>25 Q. All right. So just so I understand your</p>
<p style="text-align: right;">Page 650</p> <p>1 speculate. I would -- I am of the opinion a patient has</p> <p>2 the right to have that information available to her for</p> <p>3 her own body to make her own choice.</p> <p>4 Q. Had Mrs. Wheeler had a native tissue repair or</p> <p>5 an abdominal sacrocolpopexy procedure, would you agree</p> <p>6 with me that she could have experienced the same issues</p> <p>7 and complications she's complaining about now in her</p> <p>8 complaint?</p> <p>9 MS. GAYLE: Objection. Form. Assumes -- also,</p> <p>10 objection, assumes facts not in evidence.</p> <p>11 BY THE WITNESS:</p> <p>12 A. I disagree.</p> <p>13 Q. You disagree?</p> <p>14 A. (No verbal response.)</p> <p>15 Q. So let me explore that. So if Mrs. Wheeler</p> <p>16 had a native tissue repair for her anterior and</p> <p>17 posterior defects, you don't agree that she could have</p> <p>18 experienced pelvic pain and dyspareunia after that</p> <p>19 procedure?</p> <p>20 A. Same answers that we went down before with the</p> <p>21 first one, Alonso, applies here. Number one,</p> <p>22 Ms. Wheeler would never have had a mesh extrusion. If</p> <p>23 you had a native repair, it's impossible. It's not</p> <p>24 going to happen.</p> <p>25 Q. Right. That's why I didn't ask you about it.</p>	<p style="text-align: right;">Page 652</p> <p>1 answer, so Mrs. Wheeler still could have experienced</p> <p>2 pelvic pain and dyspareunia. But, in your opinion, it</p> <p>3 would not have been to the same degree as she's</p> <p>4 experiencing per her testimony today, correct?</p> <p>5 MS. GAYLE: Object -- objection to form and</p> <p>6 objection, mischaracterizes his testimony.</p> <p>7 BY THE WITNESS:</p> <p>8 A. It's not just my opinion. The literature</p> <p>9 supports it. And I forget what the second part is after</p> <p>10 the objection. I'll be quiet then because I can't</p> <p>11 recall what the last part of it was.</p> <p>12 Q. So let me ask my question again. You don't</p> <p>13 disagree with me, do you, Dr. Elliott, that Mrs. Wheeler</p> <p>14 could have experienced pelvic pain and dyspareunia after</p> <p>15 having a native tissue or an ASC procedure?</p> <p>16 MS. GAYLE: Objection. Asked and answered.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Again, with the qualifiers of the severity,</p> <p>19 the frequency, the location, and the delayed onset and</p> <p>20 the permanency and the inability to fix it, then I agree</p> <p>21 with you. If you take away those qualifiers, then I</p> <p>22 disagree with you.</p> <p>23 Q. Understood. Similar question to what I asked</p> <p>24 you for Mrs. Alonso. Had Mrs. Wheeler had a</p> <p>25 transvaginal mesh implanted by another medical device</p>

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<p style="text-align: right;">Page 653</p> <p>1 company, would you agree with me that she could still</p> <p>2 have experienced the same exact problems that she's</p> <p>3 complaining about today as a result of the implant of</p> <p>4 the Bard Avaulta products?</p> <p>5 <b>A. And I'll have to give the similar answer and</b></p> <p>6 <b>refer to my previous testimony on Alonso, but it's going</b></p> <p>7 <b>to be the same apply here because the Avaulta Solo</b></p> <p>8 <b>has -- is heavyweight, small pore arms compared to the</b></p> <p>9 <b>other products out there that I am familiar with, then</b></p> <p>10 <b>we can reasonably say, based upon the literature like</b></p> <p>11 <b>Clobb -- Cobb, Klosterhalfen, and others, that the</b></p> <p>12 <b>potential for complications will be greater with the</b></p> <p>13 <b>Avaulta Solo than the other mesh products. However, the</b></p> <p>14 <b>mesh -- other mesh products have a high degree of</b></p> <p>15 <b>complications with it. And it is my opinion no</b></p> <p>16 <b>transvaginal pelvic organ prolapse mesh, polypropylene,</b></p> <p>17 <b>with arms is safe.</b></p> <p>18 <b>Q. Okay. So, in this case, Mrs. Wheeler's case,</b></p> <p>19 <b>you can't say that her outcome would have been any</b></p> <p>20 <b>different had she been implanted with another type of</b></p> <p>21 <b>pelvic organ prolapse device?</b></p> <p>22 <b>MS. GAYLE: Objection. Form.</b></p> <p>23 <b>BY MS. GEIST:</b></p> <p>24 <b>Q. Correct?</b></p> <p>25 <b>A. That's what I just stated.</b></p>	<p style="text-align: right;">Page 655</p> <p>1 inflammation and decreased the risk of erosion?</p> <p>2 <b>A. Number one, I do not recall ever seeing any</b></p> <p>3 <b>literature that supports that. I would like to see it.</b></p> <p>4 <b>That would be very interesting to read. But I did</b></p> <p>5 <b>review the other ones, roughly, 15 or 20 other articles,</b></p> <p>6 <b>talking about collagen placed in the woman's vagina</b></p> <p>7 <b>increases the immune system, increases hypersensitivity,</b></p> <p>8 <b>graft versus host disease, et cetera.</b></p> <p>9 <b>Q. So you didn't -- in reaching this opinion, you</b></p> <p>10 <b>didn't review any literature or any article that</b></p> <p>11 <b>concluded that a collagen coating decreases an</b></p> <p>12 <b>inflammatory response during healing, which should, as a</b></p> <p>13 <b>result, decrease the risk of erosion?</b></p> <p>14 <b>MS. GAYLE: Objection. Form.</b></p> <p>15 <b>BY THE WITNESS:</b></p> <p>16 <b>A. I would like to see that information. In my</b></p> <p>17 <b>review of the Bard internal documents, Bard depositions,</b></p> <p>18 <b>review of the available medical literature, I have not</b></p> <p>19 <b>found that. I have seen claims on Bard documentations,</b></p> <p>20 <b>but I have not seen any data to support that. However,</b></p> <p>21 <b>I keep an open mind. I would like to see that data.</b></p> <p>22 <b>Q. Dr. Elliott, I want to move on now to the</b></p> <p>23 <b>third case in which you provided an expert opinion,</b></p> <p>24 <b>Mrs. Bolyard's case. Does anybody need a break?</b></p> <p>25 <b>A. No. They're fine.</b></p>
<p style="text-align: right;">Page 654</p> <p>1 <b>Q. Okay.</b></p> <p>2 <b>A. I said that there is, regardless of which</b></p> <p>3 <b>company's device is placed, there is still the</b></p> <p>4 <b>possibility of devastating, irreversible complications.</b></p> <p>5 <b>The Avaulta Solo has a higher chance because of the</b></p> <p>6 <b>heavyweight, small pore arms.</b></p> <p>7 <b>Q. And before you told me earlier that you're</b></p> <p>8 <b>distinguishing the Avaulta Solo from the Avaulta Plus;</b></p> <p>9 <b>is that right?</b></p> <p>10 <b>MS. GAYLE: Objection. Form.</b></p> <p>11 <b>BY THE WITNESS:</b></p> <p>12 <b>A. That is correct on this one because it was</b></p> <p>13 <b>Avaulta Solo, which was implanted in Ms. Wheeler, did</b></p> <p>14 <b>not have the collagen implant.</b></p> <p>15 <b>Q. And, in your opinion, the</b></p> <p>16 <b>collagen/polypropylene combination puts a woman at a</b></p> <p>17 <b>greater risk for adverse events because of the collagen</b></p> <p>18 <b>addition?</b></p> <p>19 <b>A. Correct. Based upon the literature that is</b></p> <p>20 <b>available, the collagen content on the mesh, which is</b></p> <p>21 <b>backed up by internal documents from Bard, has an</b></p> <p>22 <b>increased risk for delayed healing, impaired healing.</b></p> <p>23 <b>Q. Did -- in reaching that opinion, did you</b></p> <p>24 <b>consider any literature that concluded that the addition</b></p> <p>25 <b>of the collagen actually helped and decreased</b></p>	<p style="text-align: right;">Page 656</p> <p>1 <b>Q. You keep answering for everyone, Dr. Elliott.</b></p> <p>2 <b>A. That's okay. That's okay to use this?</b></p> <p>3 <b>MS. GAYLE: You can look at it real quick.</b></p> <p>4 <b>BY MS. GEIST:</b></p> <p>5 <b>Q. Sorry. I'm making a lot of noise.</b></p> <p>6 <b>MS. GAYLE: What's our time on the record?</b></p> <p>7 <b>VIDEO TECHNICIAN: 3:39.</b></p> <p>8 <b>MS. GEIST: 3:39. What was my goal? Two hours per</b></p> <p>9 <b>case. I'm doing a lot better than I could have even</b></p> <p>10 <b>hoped.</b></p> <p>11 <b>Madame Court Reporter, please tell me what</b></p> <p>12 <b>number I'm up to.</b></p> <p>13 <b>THE REPORTER: 35.</b></p> <p>14 <b>(Elliott Deposition Exhibit No. 35</b></p> <p>15 <b>was marked for identification.)</b></p> <p>16 <b>THE WITNESS: I don't see 32 on that list. Do you</b></p> <p>17 <b>have one?</b></p> <p>18 <b>THE REPORTER: I think she skipped it.</b></p> <p>19 <b>THE WITNESS: That's fine. God is in the details.</b></p> <p>20 <b>BY MS. GEIST:</b></p> <p>21 <b>Q. Okay. Dr. Elliott, we're going to shift now</b></p> <p>22 <b>and talk about your opinions in the case of Patricia</b></p> <p>23 <b>Bolyard. And so I've marked, as Exhibit 35, a copy of</b></p> <p>24 <b>your expert report in that case. Do you need a copy,</b></p> <p>25 <b>Counsel?</b></p>

<p style="text-align: right;">Page 657</p> <p>1 MS. GAYLE: Sure.</p> <p>2 MS. GEIST: This will be 35.</p> <p>3 MS. GAYLE: Thank you.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. And, Doctor, just by way of summary, can we</p> <p>6 agree for any issues that we've already discussed with</p> <p>7 respect to Mrs. Alonso and Mrs. Wheeler, those apply,</p> <p>8 also, to Mrs. Bolyard's case to the extent they're</p> <p>9 consistent?</p> <p>10 <b>A. Correct. Correct, they are.</b></p> <p>11 Q. And can I also assume, Doctor, that your</p> <p>12 methodology that you employed in reaching your expert</p> <p>13 opinions in Mrs. Bolyard's case are the same as we</p> <p>14 already talked about extensively when we discussed</p> <p>15 Mrs. Alonso's case?</p> <p>16 <b>A. Yes. My previous testimony of the evaluation,</b></p> <p>17 <b>the differential diagnosis, will all be the same with</b></p> <p>18 <b>these. And, also, for the record, on page 2 of the</b></p> <p>19 <b>report, it's under the Subsection 2, and it's</b></p> <p>20 <b>case-specific, it says, at the time of her 2008 Avaulta</b></p> <p>21 <b>placement. It's actually July 2nd of 2010.</b></p> <p>22 Q. Correct.</p> <p>23 <b>A. There is a typographical error there.</b></p> <p>24 Q. Okay.</p> <p>25 <b>A. Just for clarification, so...</b></p>	<p style="text-align: right;">Page 659</p> <p>1 Mrs. Bolyard's case, the last page of your report there,</p> <p>2 that's the list of medical records specific to</p> <p>3 Mrs. Bolyard that you reviewed to inform your opinions</p> <p>4 in her case, correct?</p> <p>5 <b>A. Yes. On page 12, I assume you're referring</b></p> <p>6 <b>to, that is the records I reviewed.</b></p> <p>7 Q. Okay. You know what? My version, Doctor,</p> <p>8 actually doesn't have a page 12. It's actually on</p> <p>9 page 2.</p> <p>10 <b>A. Okay. It just says, Exhibits for patient of</b></p> <p>11 <b>Bolyard. It says documents reviewed, and it has a list</b></p> <p>12 <b>of medical documents.</b></p> <p>13 Q. Okay.</p> <p>14 <b>A. Actually mine is incomplete.</b></p> <p>15 Q. Did -- in your review of Mrs. Bolyard's case,</p> <p>16 did you read any depositions taken in her case other</p> <p>17 than the deposition of the plaintiff herself?</p> <p>18 <b>A. Let me go to my reliance list. All I have</b></p> <p>19 <b>listened -- listed is the deposition of Patricia</b></p> <p>20 <b>Bolyard. I don't recall someone else's deposition, I</b></p> <p>21 <b>mean.</b></p> <p>22 Q. If you had read the depositions of any of the</p> <p>23 treaters in Mrs. Bolyard's case, we would see that on</p> <p>24 this list of documents reviewed?</p> <p>25 <b>A. That's correct. It should list that. And it</b></p>
<p style="text-align: right;">Page 658</p> <p>1 Q. Thank you for that clarification. I should</p> <p>2 have asked you this for Mrs. Wheeler's report. So let</p> <p>3 me ask you for both cases, Mrs. Bolyard and</p> <p>4 Mrs. Wheeler's. These are both true and accurate copies</p> <p>5 of your report, and that's your electronic signature on</p> <p>6 both, correct?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. Any other changes or revisions or typos needed</p> <p>9 to be corrected in either report?</p> <p>10 <b>A. I believe, in Ms. Wheeler, also, on page 12,</b></p> <p>11 <b>the last paragraph, it also mentions incorrectly having</b></p> <p>12 <b>the Cook device implanted. It should be Bard device.</b></p> <p>13 Q. And that typo is in both of those</p> <p>14 case-specific reports, correct?</p> <p>15 <b>A. Correct. Yeah, there is a typographical</b></p> <p>16 <b>error.</b></p> <p>17 Q. Okay. So you've made that change on the</p> <p>18 record. And in Mrs. Wheeler's report, the copy that I</p> <p>19 marked doesn't have a copy of your CV or reliance list</p> <p>20 included in that copy. And I think, by agreement of</p> <p>21 counsel, we can just supplement that and include that to</p> <p>22 make the record complete and accurate?</p> <p>23 MS. GAYLE: That's fine with me.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Thank you. And so shifting back, again, in</p>	<p style="text-align: right;">Page 660</p> <p>1 <b>also does not list the depositions of Dr. Ross and</b></p> <p>2 <b>Dr. -- Mr. Orr either. So it's somewhat incomplete.</b></p> <p>3 <b>But specific to Bolyard, it just has deposition --</b></p> <p>4 <b>Patricia Bolyard's deposition.</b></p> <p>5 Q. Well, that -- the depositions of Dr. Ross and</p> <p>6 Orr are listed in the list of materials you reviewed</p> <p>7 provided with your generic report, correct?</p> <p>8 <b>A. That is correct, yes.</b></p> <p>9 Q. For each of these reports, you have a separate</p> <p>10 list of materials reviewed that are specific to that</p> <p>11 individual plaintiff; fair to say?</p> <p>12 <b>A. That is correct, yes.</b></p> <p>13 Q. And here for Mrs. Bolyard we don't see any</p> <p>14 indication that you reviewed any of the deposition</p> <p>15 testimony provided by any treating physicians in the</p> <p>16 case, correct?</p> <p>17 <b>A. Yeah. There is nothing listed here. I don't</b></p> <p>18 <b>recall if I reviewed something of the surgeon or not,</b></p> <p>19 <b>but there is nothing listed here.</b></p> <p>20 Q. Would that have been important information for</p> <p>21 you to review in order to inform your opinions in the</p> <p>22 case?</p> <p>23 <b>A. I think it would be --</b></p> <p>24 MS. GAYLE: Objection. Form.</p> <p>25 BY THE WITNESS:</p>



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<p style="text-align: right;">Page 661</p> <p>1 <b>A. I think it would be additive to the fund of</b>  2 <b>knowledge.</b>  3 Q. But you didn't do that in this case?  4 <b>A. I'm saying I don't recall if I did or not.</b>  5 Q. Do you know if any of the information in those  6 depositions would have changed your opinions in  7 Mrs. Bolyard's case?  8 MS. GAYLE: Objection. Form.  9 BY THE WITNESS:  10 <b>A. I would have to see those depositions.</b>  11 Q. So, sitting here today, you don't know one way  12 or another if your opinions would have been changed by  13 reviewing what the treaters had to say?  14 <b>A. I've been able to review their medical</b>  15 <b>documents. I've been able to review the medical</b>  16 <b>literature. I've been able to examine the patient</b>  17 <b>specifically. So the possibility of them altering my</b>  18 <b>opinion would be very small to none.</b>  19 Q. Okay. With respect to Mrs. Bolyard, she had  20 implanted, back on July 2nd, 2010, by Dr. Prouty the  21 Avaulta Solo anterior and posterior products, correct?  22 <b>A. That is correct.</b>  23 Q. No Align sling in this case, correct?  24 <b>A. There was no documentation of that in the</b>  25 <b>records.</b></p>	<p style="text-align: right;">Page 663</p> <p>1 <b>to lichen sclerosis. It should be pelvic skin pain.</b>  2 MS. GAYLE: Hold up one moment, Doctor. Can you  3 spell that for Madame Court Reporter.  4 <b>THE WITNESS: Oh, lichen sclerosis? L-I-C-H-E-N,</b>  5 <b>and the next word is, sclerosis, S-C-L-E-R-O-S-I-S.</b>  6 (Sic.)  7 BY MS. GEIST:  8 Q. So let's go to page 2 of your report in  9 Mrs. Bolyard's case, Doctor.  10 <b>A. Okay. I'm there.</b>  11 Q. This is a list of your opinions, correct?  12 <b>A. On page 2?</b>  13 Q. I'm on page 5.  14 <b>A. Oh, yes.</b>  15 Q. Okay. And what -- tell me, again, what  16 exactly you need to change or amend in your report with  17 respect to the -- is it lichen or lichen?  18 <b>A. Lichen sclerosis.</b>  19 Q. Lichen sclerosis?  20 <b>A. Yes. Number one, I say pelvic pain secondary</b>  21 <b>to lichen sclerosis. It's pelvic skin pain. Lichen</b>  22 <b>sclerosis is a superficial disorder of the skin. I left</b>  23 <b>out skin there. And that has -- that has not been</b>  24 <b>caused by Avaulta. It's not been provoked by Avaulta.</b>  25 <b>It's a preexisting condition.</b></p>
<p style="text-align: right;">Page 662</p> <p>1 Q. Okay. You would have seen that somewhere in  2 the records if she had an Align sling implanted to  3 relieve stress urinary incontinence symptoms, correct?  4 <b>A. It should be in there, and it was not noted.</b>  5 Q. Okay. So same question that I asked you in  6 Mrs. Wheeler's case. Any of your opinions relating to  7 the Bard Avaulta Plus product and your opinions relating  8 to the collagen-polypropylene combination product would  9 not apply to Mrs. Bolyard's case, true?  10 <b>A. That -- that is correct. Anything pertaining</b>  11 <b>specifically to the collagen implantation do not apply</b>  12 <b>to Ms. Bolyard.</b>  13 Q. And, in Mrs. Bolyard's case, like I did with  14 your other cases, I'm going to just try and summarize  15 your opinions. And in her case, your opinions are that,  16 due to the Bard Avaulta product, she is experiencing  17 pelvic pain dyspareunia, urge incontinence, pelvic floor  18 myalgia, and then we have that same paragraph regarding  19 the impact on loss of physical intimacy and potential  20 for long-term depression, correct?  21 <b>A. Correct. She also -- she -- her current</b>  22 <b>diagnosis also is pelvic skin pain secondary to lichen</b>  23 <b>sclerosus, which has nothing -- that is not caused by</b>  24 <b>the Avaulta product. That is a preexisting condition.</b>  25 <b>Again, it states, in number one, pelvic pain secondary</b></p>	<p style="text-align: right;">Page 664</p> <p>1 Q. And lichen sclerosis is a fairly rare  2 condition, would you agree with me on that?  3 <b>A. Yes, it is a rare condition.</b>  4 Q. And the symptomatology associated with lichen  5 sclerosis is burning and cutting pain in the vaginal  6 region?  7 <b>A. In the skin, yes. It's a skin disorder.</b>  8 Q. That causes burning and cutting pain, correct?  9 <b>A. On the skin, yes.</b>  10 Q. Well, it can also result in painful sexual  11 intercourse or dyspareunia, correct?  12 <b>A. It can result in insertional pain at the skin</b>  13 <b>level.</b>  14 Q. Well, that's well established by the medical  15 literature; is it not?  16 <b>A. Yes. But the clarifier on there, it does not</b>  17 <b>cause pelvic floor myalgia. It does not cause deep</b>  18 <b>insertional pain. It's superficial skin pain at the</b>  19 <b>level of the introitus.</b>  20 Q. But you would agree with me, as set forth here  21 in your expert report in Mrs. Bolyard's case, that this  22 is a separate and independent reason for Mrs. Bolyard's  23 pelvic pain that has nothing to do with the Bard Avaulta  24 products; is that true?  25 <b>A. Bard is not responsible for causing lichen</b></p>



<p style="text-align: right;">Page 665</p> <p>1 <b>sclerosis, not cause for flare-up of the lichen</b>  2 <b>sclerosis. This is a skin disorder on the outside of</b>  3 <b>the vagina, which, again, has not been caused by Bard</b>  4 <b>products.</b>  5 Q. And this is a condition that Mrs. Bolyard will  6 unfortunately have for the remainder of her life, true?  7 <b>A. To date there is no known cure for this</b>  8 <b>process.</b>  9 Q. And I assume you saw in the medical records  10 that, prior to her implant of the Bard products, she had  11 rated her dyspareunia pain as a 7 out of 10, and that is  12 caused by the lichen sclerosis, correct?  13 <b>A. Correct. And that is insertional pain, a 7 on</b>  14 <b>the Visual Analog Scale at the level of the skin. I</b>  15 <b>agree with you.</b>  16 Q. And I believe she told you, when you saw her  17 and conducted your independent medical evaluation, that  18 her dyspareunia could be rated as an 8 out of 10; is  19 that correct?  20 <b>A. Where the -- we have to be careful, as far as</b>  21 <b>what we're defining, I'm being very clear that Avaulta</b>  22 <b>and Bard products are not responsible for lichen</b>  23 <b>sclerosis. They are responsible for the deep pain</b>  24 <b>inside of Ms. Bolyard's vagina.</b>  25 Q. Well, we can agree, from the medical records,</p>	<p style="text-align: right;">Page 667</p> <p>1 <b>that pain is.</b>  2 Q. Is there any distinguishing information in her  3 medical records that talk about the location of the  4 pain, or does she just say, I have had pain -- painful  5 sexual intercourse before ever being implanted with the  6 Bard product that I rate on a scale of 7 out of 10?  7 MS. GAYLE: Object to form.  8 BY THE WITNESS:  9 <b>A. Well, lichen sclerosis is a disease of the</b>  10 <b>skin. It's not a disease of the vagina. So it is in</b>  11 <b>the medical records. There is no reason for her to have</b>  12 <b>deep vaginal pain or obturator foramen pain, but she</b>  13 <b>would have skin pain.</b>  14 Q. And she complains of this in terms of painful  15 sexual intercourse preimplant? That's in the records,  16 correct?  17 <b>A. Correct.</b>  18 Q. And then, after the surgery in July of 2010  19 where Mrs. Bolyard was implanted with the Bard products,  20 we see that she is now complaining of dyspareunia pain  21 and she rates it as an 8, 8 out of 10, postimplant,  22 correct?  23 <b>A. That is what I state, yes.</b>  24 Q. Okay. So we've moved from 7 out of 10  25 preimplant to 8 out of 10 postimplant?</p>
<p style="text-align: right;">Page 666</p> <p>1 that Mrs. Bolyard's lichen sclerosis was causing her, as  2 reflected in her records, painful intercourse or  3 dyspareunia and she rated it as a 7 out of 10  4 preimplant, correct?  5 <b>A. Correct, at the level of the skin.</b>  6 Q. Well, she --  7 <b>A. The introitus.</b>  8 Q. -- doesn't say anywhere in her records -- she  9 doesn't distinguish dyspareunia, as you are now, by  10 saying, well, it's only at the level of the skin, does  11 she?  12 MS. GAYLE: Object to form and move to strike.  13 BY THE WITNESS:  14 <b>A. Lichen sclerosis is not a disorder on the</b>  15 <b>inside of the vagina. It will not distort the vagina.</b>  16 <b>It will distort the introitus, the opening of the</b>  17 <b>vagina.</b>  18 Q. Understood. But in Mrs. Bolyard's own  19 records, she has told her treating doctors, prior to  20 ever being implanted with the Bard product, that her  21 dyspareunia pain could be rated on a scale of 0 to 10.  22 She rated it as a 7 out of 10. That's what the records  23 show, correct?  24 <b>A. Yes. The records state that and with the</b>  25 <b>understanding we have to define where the location of</b></p>	<p style="text-align: right;">Page 668</p> <p>1 MS. GAYLE: Object to form.  2 BY MS. GEIST:  3 Q. Fair summary?  4 <b>A. But there is a location difference, but the</b>  5 <b>overall pain level has increased.</b>  6 Q. Can you point me to any medical record that  7 supports what you just told me, that there is a  8 difference in where she's experiencing the pain?  9 <b>A. Well, it's based upon my exam of her.</b>  10 Q. Well, her medical records, prior to her  11 implant, just say, I have pain with sexual intercourse.  12 I rate it as a 7 out of 10; isn't that true?  13 MS. GAYLE: Object to form.  14 BY THE WITNESS:  15 <b>A. Well, prior to the surgery, and the surg- --</b>  16 <b>the doctor is just documenting that she has painful</b>  17 <b>intercourse.</b>  18 Q. Right.  19 <b>A. They have not delineated where that pain is.</b>  20 Q. Okay. Let's shift and talk about  21 Mrs. Bolyard's smoking history. I noted, when you  22 provided us with your updated literature list and  23 bibliography, you had some articles on there relating to  24 smoking and the potential injury or impact smoking could  25 have on the human body?</p>

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<p style="text-align: right;">Page 669</p> <p>1 <b>A. Correct.</b></p> <p>2 Q. Did you do a little bit more reading about</p> <p>3 smoking and the potential negative impact smoking could</p> <p>4 have on the human body in preparation for your</p> <p>5 deposition?</p> <p>6 MS. GAYLE: Objection. Form. His opinions</p> <p>7 regarding smoking were discussed yesterday. If you have</p> <p>8 a specific question in relation to this patient, go</p> <p>9 ahead.</p> <p>10 MS. GEIST: I am --</p> <p>11 MS. GAYLE: But it sounded in general to me.</p> <p>12 MS. GEIST: I think I'm entitled to get an answer</p> <p>13 here. So I hope you're not instructing Dr. Elliott to</p> <p>14 not answer my question.</p> <p>15 MS. GAYLE: I believe that's a general opinion, but</p> <p>16 I didn't hear anything case specific with her. I think</p> <p>17 you started off and then tailed off. But if you want to</p> <p>18 read back the question, you can, but I believe it to be</p> <p>19 a general question.</p> <p>20 MS. GEIST: Can you read back my question?</p> <p>21 MS. GAYLE: And the one before, Madam Court</p> <p>22 Reporter.</p> <p>23 THE REPORTER: I'm sorry.</p> <p>24 MS. GAYLE: And the one before it.</p> <p>25 (Record read as requested.)</p>	<p style="text-align: right;">Page 671</p> <p>1 transvaginal cases with meshes. There is no data that I</p> <p>2 am aware of that smoking increases any wound healing in</p> <p>3 nonsmoker's transvaginal repairs.</p> <p>4 Q. So if Mrs. Bolyard had had an abdominal</p> <p>5 sacrocolpopexy instead of a transvaginal mesh procedure</p> <p>6 to treat her anterior and posterior defects, she would</p> <p>7 have been at an even greater risk of mesh extrusion as</p> <p>8 demonstrated by the literature, correct?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A. Incorrect. The literature is current smokers.</b></p> <p>12 <b>There is no data out there that I am aware of on former</b></p> <p>13 <b>smokers.</b></p> <p>14 Q. So --</p> <p>15 <b>A. But current and active smokers are at</b></p> <p>16 <b>increased risk.</b></p> <p>17 Q. So a woman who is an active smoker at the time</p> <p>18 of her procedure is at an increased risk?</p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 <b>A. For transvaginal repairs, but there is also</b></p> <p>22 <b>good data out there that stopping up to ten days prior</b></p> <p>23 <b>reduces that risk tremendously. So, again, in former</b></p> <p>24 <b>smokers, I know of no good data that says they're at an</b></p> <p>25 <b>increased risk.</b></p>
<p style="text-align: right;">Page 670</p> <p>1 MS. GAYLE: My objection stands.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. All right. So let me just add, in preparation</p> <p>4 for your deposition in this case, in Mrs. Bolyard's</p> <p>5 case, where we have a plaintiff who has a very</p> <p>6 significant and extensive history of smoking?</p> <p>7 MS. GAYLE: Thank you, Counsel.</p> <p>8 MS. GEIST: You're welcome.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A. I did not update my reliance or look at</b></p> <p>11 <b>documents in preparation for a deposition because I also</b></p> <p>12 <b>do sacrocolpopexies. Smoking is associated with an</b></p> <p>13 <b>increased risk of mesh extrusion, that I know of no data</b></p> <p>14 <b>that states that smoking is involved in impaired healing</b></p> <p>15 <b>with nonmeshes. So I have a natural interest in that.</b></p> <p>16 Q. Okay. So let me just make sure I understand</p> <p>17 that. Mrs. Bolyard, because of her long-term and</p> <p>18 extensive history of smoking, was at a greater risk for</p> <p>19 mesh expulsion -- pardon me -- mesh exposure or erosion</p> <p>20 as a result of her smoking history; is that fair to say?</p> <p>21 MS. GAYLE: Objection, form.</p> <p>22 BY THE WITNESS:</p> <p>23 <b>A. There is data in the sacrocolpopexy that</b></p> <p>24 <b>smoking can increase the risk of extrusion. I have</b></p> <p>25 <b>heard conflicting reports as far as with the</b></p>	<p style="text-align: right;">Page 672</p> <p>1 Q. Well, Doctor, is Mrs. Bolyard a former smoker?</p> <p>2 <b>A. It states in here former smoker. And that</b></p> <p>3 <b>actually raises a good point. I would have to look at</b></p> <p>4 <b>the IFU to see if they warn. If there is data out</b></p> <p>5 <b>there, I would like to see it. Because if there is good</b></p> <p>6 <b>data out there that smoking increases risk of extrusion</b></p> <p>7 <b>or complications with meshes, then it should be in the</b></p> <p>8 <b>IFU. And to the best of my knowledge, and correct me if</b></p> <p>9 <b>I'm wrong, I have not read any deposition. There is</b></p> <p>10 <b>nothing in here about smoking. So I would like to know,</b></p> <p>11 <b>is there information out there.</b></p> <p>12 Q. But just so I'm clear, it's your opinion that</p> <p>13 somebody who is a current smoker is at a higher risk or</p> <p>14 at an increased risk of mesh extrusion based on the</p> <p>15 smoking, correct?</p> <p>16 MS. GAYLE: Objection. Form. Mischaracterizes his</p> <p>17 testimony.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A. The data that I am familiar with is in</b></p> <p>20 <b>abdominal sacrocolpopexies current smokers there is</b></p> <p>21 <b>increased risk. I am not aware of consistent or</b></p> <p>22 <b>consistent -- consistent on transvaginal mesh repairs.</b></p> <p>23 Q. Any reason to think the data would be any</p> <p>24 different or better with the transvaginal repair?</p> <p>25 <b>A. Yes, because they're a different procedure.</b></p>

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<p style="text-align: right;">Page 673</p> <p>1 Q. Well, smoking, it has a negative impact and</p> <p>2 damages the vasculature, correct?</p> <p>3 <b>A. Correct. I think that that's a fair</b></p> <p>4 <b>assessment.</b></p> <p>5 Q. And somebody who has a pack-a-day habit is at</p> <p>6 a greater risk of damage to the vascular -- vasculature</p> <p>7 than somebody who has a half pack a day compared to</p> <p>8 somebody who smokes a cigarette or two a day?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. The more cigarettes you smoke, the more damage</p> <p>12 you're causing to your body? Isn't that something</p> <p>13 that's noncontroversial, Doctor?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 <b>A. I don't know if there is any data that says at</b></p> <p>17 <b>what point in time you cross that threshold of their</b></p> <p>18 <b>being dangerous. And, again, I am reviewing the IFU</b></p> <p>19 <b>right now, and I see nowhere in here a warning on</b></p> <p>20 <b>smokers.</b></p> <p>21 Q. Well, Doctor, come on. Do you need a warning</p> <p>22 in the IFU about smoking? Doesn't every medical doctor</p> <p>23 who has gone through medical school and gone on to treat</p> <p>24 patients know that smoking is dangerous and damages</p> <p>25 your -- damages your system, your vasculature? You</p>	<p style="text-align: right;">Page 675</p> <p>1 information about smoking and that that would have been</p> <p>2 information a doctor would need to read about in order</p> <p>3 to be informed about the risk of smoking?</p> <p>4 <b>A. I think it's not just my opinion. It's the</b></p> <p>5 <b>FDA's opinion, and a patient needs to be aware that, if</b></p> <p>6 <b>they are smoking, they are at an increased risk.</b></p> <p>7 Q. You've never worked with the FDA or been a</p> <p>8 consultant to the FDA with respect to what needs to go</p> <p>9 into an IFU or not go into an IFU, correct?</p> <p>10 MS. GAYLE: Objection. Form. This was ground that</p> <p>11 we plowed yesterday.</p> <p>12 BY MS. GEIST:</p> <p>13 Q. Is that correct, Doctor? You've never been a</p> <p>14 consultant for the FDA or worked with the FDA on what</p> <p>15 should go into an IFU?</p> <p>16 MS. GAYLE: Same objection. I'm going to instruct</p> <p>17 you not to answer that because you asked it yesterday.</p> <p>18 MS. GEIST: I didn't ask him that question</p> <p>19 yesterday. We didn't talk about FDA consulting. And he</p> <p>20 just raised FDA regulations and an opinion about what</p> <p>21 the FDA would require. So my question is new.</p> <p>22 BY MS. GEIST:</p> <p>23 <u>Q. Have you ever been a consultant or worked for</u></p> <p>24 <u>the FDA in -- on issues relating to what should be on a</u></p> <p>25 <u>label or an IFU?</u></p>
<p style="text-align: right;">Page 674</p> <p>1 don't need to be told that in the IFU, do you?</p> <p>2 MS. GAYLE: Move to strike the preface to questions</p> <p>3 by counsel. Also, objection. Argumentative.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A. According to the FDA Blue Book, the warning</b></p> <p>6 <b>sections, if a company is aware, they have to warn the</b></p> <p>7 <b>patients of all known issues. If smoking -- if they</b></p> <p>8 <b>know smoking is increasing the risk of complications</b></p> <p>9 <b>with the procedure, they have to warn it. They do warn</b></p> <p>10 <b>with their trocars of the possibility of organ</b></p> <p>11 <b>perforation. If I hold up a trocar and you look at it,</b></p> <p>12 <b>that will perforate organs. You don't need any degree</b></p> <p>13 <b>with that, but they warn it. So, subsequently, smoking,</b></p> <p>14 <b>I don't know. So, again, it's not in here.</b></p> <p>15 Q. Since you raised the point, there is no</p> <p>16 evidence that there was any trocar perforation or any</p> <p>17 damage caused to Mrs. Alonso or Mrs. Wheeler or</p> <p>18 Mrs. Bolyard based on the trocars used in any of those</p> <p>19 cases, correct?</p> <p>20 MS. GAYLE: Object to form.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A. There is no evidence of organ perforation with</b></p> <p>23 <b>all three of those that you mentioned from the trocars.</b></p> <p>24 Q. All right. So let's go back to smoking. Is</p> <p>25 it your opinion that the IFU should have contained</p>	<p style="text-align: right;">Page 676</p> <p>1 <u><b>A. I've --</b></u></p> <p>2 <u><b>MS. GAYLE: Same objection.</b></u></p> <p>3 <u><b>BY THE WITNESS:</b></u></p> <p>4 <u><b>A. I have never been an employee of the FDA.</b></u></p> <p>5 <u><b>Q. Or a consultant with respect to the IFU or</b></u></p> <p>6 <u><b>what information needs to go into a label?</b></u></p> <p>7 <u><b>A. I have never been an employee nor a consultant</b></u></p> <p>8 <u><b>of the FDA.</b></u></p> <p>9 Q. Now, back to smoking, would you agree with me</p> <p>10 that the duration or the length of time that somebody</p> <p>11 smokes would have an increase on the damage to the</p> <p>12 vasculature; in other words, if somebody -- if somebody</p> <p>13 who smokes for five years compared to somebody who</p> <p>14 smokes for ten years or, in Mrs. Bolyard's case,</p> <p>15 somebody who smokes for 50 years a pack a day, are they</p> <p>16 not at a greater increased risk for damaging their own 17</p> <p>17 vasculature system?</p> <p>18 <b>A. I think the data supports not necessarily the 19</b></p> <p>19 <b>duration of smoking, but the fact that an individual 20</b></p> <p>20 <b>stops smoking.</b></p> <p>21 Q. Now, you keep saying that, Doctor.</p> <p>22 <b>A. Because --</b></p> <p>23 Q. Is your -- I'm sorry. Were you not done?</p> <p>24 <b>A. No. I'm sorry.</b></p> <p>25 Q. Is it your opinion that Mrs. Bolyard had</p>

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<p style="text-align: right;">Page 677</p> <p>1 stopped smoking before she was implanted with the Bard 2 Avaulta products? 3 <b>A. I would have to go back and look at the</b> 4 <b>literature. I don't recall. I'm going off of my notes</b> 5 <b>here, and it states she was a former smoker.</b> 6 Q. Well, what makes you think she was a former 7 smoker? 8 <b>A. I would have to look at the notes. At some</b> 9 <b>point in time, I must have saw that she had stopped</b> 10 <b>smoking.</b> 11 Q. If she was a current smoker at the time of her 12 implant surgery back in July of 2010, would that change 13 your opinions in the case? 14 <b>A. If -- if the consensus is that that's going to</b> 15 <b>impair healing, then it would change it because that's</b> 16 <b>all the more evidence it should have been on the IFU.</b> 17 Q. Isn't it well-known by the medical community 18 that smokers have a greater challenge with healing, 19 their healing is impaired because of their smoking, 20 current smokers? 21 MS. GAYLE: Objection. Form. 22 BY THE WITNESS: 23 <b>A. Not with transvaginal work without meshes.</b> 24 <b>There is no data to support that.</b> 25 Q. There is no data to support that?</p>	<p style="text-align: right;">Page 679</p> <p>1 Q. All right. 2 <b>A. But we're -- but we're not --</b> 3 Q. So, at least, there is some -- I'm sorry. Go 4 ahead? 5 <b>A. We are talking about native, non-mesh repairs.</b> 6 <b>I know of zero data that smoking increases the problems</b> 7 <b>of wound healing.</b> 8 Q. But you have seen that data in the context of 9 the abdominal sacrocolpopexy, which is a mesh procedure 10 done via the abdominal approach, correct? 11 <b>A. Which we have discussed the other day as a</b> 12 <b>completely separate procedure and it's transabdominal.</b> 13 Q. But you have seen that data, correct? 14 <b>A. Correct, for the transabdominal repair, but</b> 15 <b>not the transvaginal repair.</b> 16 Q. So can we agree that Mrs. Bolyard, had she had 17 the trans- -- sorry -- had she had the abdominal 18 sacrocolpopexy instead of the transvaginal mesh, she 19 would have been at an increased risk of erosion after 20 that operation? 21 MS. GAYLE: Object to form. 22 BY THE WITNESS: 23 <b>A. Well, you used the word erosion. It's</b> 24 <b>extrusion.</b> 25 Q. Sorry. Extrusion.</p>
<p style="text-align: right;">Page 678</p> <p>1 <b>A. Zero data with transvaginal native repairs</b> 2 <b>that impairs healing.</b> 3 Q. But you don't think you can extrapolate the 4 general, well-established body of literature out there 5 that says smoking is bad and damages your vasculature 6 and causes challenges and delayed healing? You can't 7 take that literature and say, well, of course, those 8 same problems and challenges would apply to somebody 9 undergoing a transvaginal mesh surgery? You can't do 10 that? 11 MS. GAYLE: Objection. Form. 12 BY THE WITNESS: 13 <b>A. Studies have been done and they don't see an</b> 14 <b>independent variable study analysis on transvaginal work</b> 15 <b>to show that smoking increases the risk of poor wound</b> 16 <b>healing in transvaginal work without meshes.</b> 17 Q. Are there some studies -- are there some 18 studies that talk about the fact that smoking may 19 increase a problem with healing or result in delayed 20 healing in somebody who has had a transvaginal mesh 21 implanted? 22 <b>A. With meshes, I have seen some state -- some</b> 23 <b>data -- I have seen some data stating that it can</b> 24 <b>increase the risk and other data showing it does not</b> 25 <b>have any impact upon it.</b></p>	<p style="text-align: right;">Page 680</p> <p>1 <b>A. The data that -- there is data out there. If</b> 2 <b>she would have had a different procedure and had the</b> 3 <b>abdominal sacrocolpopexy, that there would have been an</b> 4 <b>increased risk for extrusion in that procedure, which</b> 5 <b>she did not have.</b> 6 Q. And sitting here today, after reviewing 7 Mrs. Bolyard's medical records, it's your opinion that 8 she was not a current smoker at the time she had her 9 Bard Avaulta mesh implanted or any time thereafter? 10 MS. GAYLE: Objection. Form and asked and 11 answered. 12 BY THE WITNESS: 13 <b>A. I would have to go back and look at the</b> 14 <b>records. You know, according to my notes, I wrote down</b> 15 <b>here, it says that she was a former smoker.</b> 16 Q. Well, if the records show -- if you go back 17 again and you take a look and you see that the records 18 show that Mrs. Bolyard was a current smoker at the time 19 of her Bard -- at the time of her implant surgery and 20 continued to smoke thereafter, would that change your 21 opinions in this case concerning the causes of the 22 problems that she experienced after the implant? 23 MS. GAYLE: Objection to form. 24 BY THE WITNESS: 25 <b>A. Well, as I mentioned, according to my</b></p>

<p style="text-align: right;">Page 681</p> <p>1 knowledge, there is conflicting data smoking does  2 anything as far as transvaginal mesh work. And if she  3 were an active smoker and there is knowledge out there  4 by the company that that is going to impair healing,  5 that's got to be on the IFU and she's got to be warned  6 for that.</p> <p>7 Q. So if you -- if you go back and you take  8 another look at the records, Doctor, and you conclude  9 that Mrs. Bolyard was a current smoker at the time of  10 the implant, that wouldn't have any impact or change  11 your opinions in this case, whatsoever; is that what  12 you're telling me?</p> <p>13 MS. GAYLE: Objection. Objection. Form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Well, I thought I just answered it. Because  16 in the precautions section of the IFU, they list things  17 about compromised immune system, prior abdominal pelvic  18 surgeries, they list quite a few issues here, but  19 nowhere in there is, again, smoking. So from Bard's  20 perspective, it must not have played a role.</p> <p>21 Q. If you go back and look at Mrs. Bolyard's  22 records and conclude that she was a current smoker at  23 the time of her surgery, would you consider that fact in  24 reaching your opinions regarding why she experienced the  25 complications that she's testified about?</p>	<p style="text-align: right;">Page 683</p> <p>1 A. CO --</p> <p>2 Q. Would you consider Mrs. Bolyard's COPD and  3 chronic cough in reaching your opinions in this case  4 that the Bard Avaulta products were the cause of her  5 complications?</p> <p>6 A. COPD, in and of itself, is a lung condition  7 which would have no bearing upon vaginal extrusion,  8 vaginal pain. It may increase the risk of recurrence of  9 a prolapse, but it's not going to cause the other  10 issues.</p> <p>11 Q. How about --</p> <p>12 MS. GAYLE: Before your next question, do you  13 mind if we take a short break? I think it would do  14 us all good because everybody is stuttering and so  15 forth.</p> <p>16 MS. GEIST: No, not at all. I'm happy to take a  17 break.</p> <p>18 VIDEO TECHNICIAN: We're off the record. The time  19 is 1:55 p.m.</p> <p>20 (A recess was had.)</p> <p>21 VIDEO TECHNICIAN: We're back on the record. The  22 time is 2:03 p.m.</p> <p>23 MS. GEIST: May I have my last question read back,  24 please, Madam Court Reporter.</p> <p>25 (Record read as requested.)</p>
<p style="text-align: right;">Page 682</p> <p>1 MS. GAYLE: Objection. Asked and answered.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I believe I've answered. I guess I'm confused  4 because I've been answering this multiple times. I  5 would have to look --</p> <p>6 Q. I wouldn't be asking it again, Dr. Elliott, if  7 you would answer my questions. And this has been going  8 on all day today and all day yesterday. If you would  9 answer my questions, we could move on. I just want to  10 know. I just want to know, did you consider the fact  11 that Mrs. Bolyard was a current smoker at the time of  12 the implant and had a 50-year, pack-a-day history, did  13 you consider that as an alternative cause of some of the  14 problems and complications she experienced after her  15 implant surgery?</p> <p>16 MS. GAYLE: Objection. Asked and answered.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I have in my notes here she is a former  19 smoker. I have no evidence of her being an active  20 smoker at the time of the implantation. So if you show  21 me data that she was an active smoker at the surgery,  22 then we can proceed. Otherwise, I'm going off of what  23 my notes are.</p> <p>24 Q. How about chronic obstructive pulmonary  25 disease or COPD?</p>	<p style="text-align: right;">Page 684</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Doctor, would somebody such as Mrs. Bolyard  3 who has a chronic cough as a result of her COPD be at a  4 greater risk for erosion or extrusion of the vaginal  5 mesh?</p> <p>6 A. I'm not aware of any data that would show for  7 extrusion of mesh, it increased risk of recurrence of  8 her prolapse.</p> <p>9 Q. Would you agree with me if she had had, for  10 example, a native tissue repair, because the native  11 tissue repair is not augmented with a synthetic mesh,  12 that she would have had a greater recurrence of prolapse  13 had she undergone that procedure based on her chronic  14 cough?</p> <p>15 A. Chronic cough is associated with a greater  16 recurrence of pelvic organ prolapse. I'm not aware of  17 any study comparing COPD and native and mesh repairs.</p> <p>18 So I can't say if she would have a greater recurrence.</p> <p>19 Q. If she had had a native tissue, you can't say,  20 due to her chronic cough, that she would have had a  21 recurrence of the prolapse repaired by the native tissue  22 procedure?</p> <p>23 A. She -- she would have a higher chance of  24 recurrence of a pelvic organ prolapse regardless of what  25 type of repair she had because it's a chronic,</p>



<p style="text-align: right;">Page 685</p> <p>1 <b>repetitive process.</b></p> <p>2 Q. How about diabetes? Does somebody diagnosed</p> <p>3 with diabetes have greater challenges with respect to</p> <p>4 healing after a surgical procedure?</p> <p>5 A. I'm not aware of anything transvaginal as far</p> <p>6 as increasing wound healing. Definitely transabdominal</p> <p>7 and obesity can increase the risk of wound healing, but</p> <p>8 that's on the abdomen and the skin.</p> <p>9 Q. Did you consider, in reaching your</p> <p>10 differential, whether Mrs. Bolyard's diagnosis of</p> <p>11 diabetes could have had an impact on her wound healing?</p> <p>12 A. Yes.</p> <p>13 Q. And did you eliminate that as a cause after</p> <p>14 you considered it?</p> <p>15 A. Well, diabetes -- I am unaware of any study</p> <p>16 demonstrating that diabetes, in the transvaginal mesh</p> <p>17 group, increases the risk of extrusion. In my review of</p> <p>18 the literature and my experience, I have not seen</p> <p>19 anything like that. If there is data, I would like to</p> <p>20 see it. So, yes, I did review that. I did consider it.</p> <p>21 I did not find it being, based upon data, a causal</p> <p>22 factor.</p> <p>23 Q. Only because you couldn't find any data</p> <p>24 specific to a transvaginal -- strike that.</p> <p>25 Only because you couldn't find any data that</p>	<p style="text-align: right;">Page 687</p> <p>1 to realize and that's why you need to have a very good</p> <p>2 understanding of neuroanatomy, which is exactly why, in</p> <p>3 my fellowship on bladder and neuroanatomy and a member</p> <p>4 of the International Pelvic Pain Society, you have to</p> <p>5 look at the distribution of the nerves, where the nerves</p> <p>6 go.</p> <p>7 Pain down the legs, the back of the leg, the</p> <p>8 bottom of the foot, that type of pain is consistent with</p> <p>9 degenerative disc disease that is not caused by an</p> <p>10 Avaulta product. Pain inside the vagina at the</p> <p>11 obturator foramen is not due to degenerative disc</p> <p>12 disease.</p> <p>13 Q. So you don't think any of the pain complaints</p> <p>14 that Mrs. Bolyard has can be attributed to the</p> <p>15 degenerative disc disease? Is that your opinion?</p> <p>16 A. We have to be specific which pain we're</p> <p>17 talking about. If we're talking about dyspareunia pain</p> <p>18 on pelvic exam, that is not due to a degenerative disc</p> <p>19 disease.</p> <p>20 Q. How about her generalized complaints of pelvic</p> <p>21 pain?</p> <p>22 MS. GAYLE: Objection.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. Could that be attributable to her degenerative</p> <p>25 disc disease?</p>
<p style="text-align: right;">Page 686</p> <p>1 specifically looked at the impact of diabetes on wound</p> <p>2 healing after a transvaginal surgery?</p> <p>3 MS. GAYLE: Objection. Form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. No. There are many studies out there,</p> <p>6 multivariate analysis studies, looking at diabetes, age,</p> <p>7 obesity, transvaginal repairs, and also mesh repairs. I</p> <p>8 have yet to see anything on a good quality, multivariate</p> <p>9 study to demonstrate diabetes increases the risk of</p> <p>10 vaginal extrusion.</p> <p>11 Q. But you agree that diabetes increases the risk</p> <p>12 or increases problems associated with wound healing,</p> <p>13 correct?</p> <p>14 A. In the setting of the abdomen.</p> <p>15 Q. Why wouldn't that apply to the vaginal</p> <p>16 setting?</p> <p>17 A. Because there is no fat in the vagina. Fat is</p> <p>18 the problem. Fat does not heal. There is no fat, no</p> <p>19 adipose, in the vagina.</p> <p>20 Q. How about degenerative disc disease? Did you</p> <p>21 consider Mrs. Bolyard's degenerative disc disease --</p> <p>22 A. Absolutely.</p> <p>23 Q. -- in reaching your opinions with respect to</p> <p>24 her chronic pain?</p> <p>25 A. Absolutely. And that is a very important one</p>	<p style="text-align: right;">Page 688</p> <p>1 A. Degenerative disc disease usually is L2 --</p> <p>2 excuse me, L3, 4, 5. The nerve roots of that extend</p> <p>3 down to the sciatic, which then extend down the back of</p> <p>4 the leg, front of the thigh, and the bottom of the foot.</p> <p>5 And that is not the type of pain that she is</p> <p>6 experiencing in the pelvis. The nerves have to be</p> <p>7 involved going to the pelvis and they are not. Because</p> <p>8 then we're talking about the pudendal nerve, and we have</p> <p>9 no evidence of that being involved.</p> <p>10 Q. It's your opinion, Dr. Elliott, from your</p> <p>11 expert report, that her pelvic pain is caused, at least,</p> <p>12 in some degree, by her lichen sclerosis, correct?</p> <p>13 MS. GAYLE: Objection. Form. I believe he</p> <p>14 corrected that on the report earlier.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Pelvic skin pain, peroneum pain on the skin is</p> <p>17 definitely due to lichen sclerosis. Avaulta, to the</p> <p>18 best of my knowledge based upon neuroanatomy, study of</p> <p>19 pelvic nerve neuroanatomy, the Avaulta product will not</p> <p>20 be affecting the skin of the peroneum.</p> <p>21 Q. So explain to me this difference you've been</p> <p>22 talking about, the pelvic skin pain versus pelvic pain</p> <p>23 generally. If I understand your report, you say that</p> <p>24 the -- and this is based on your revision that we did</p> <p>25 earlier, Mrs. Bolyard's pelvic skin complaint is</p>

<p style="text-align: right;">Page 689</p> <p>1 secondary or caused by the lich- --</p> <p>2 <b>A. Lichen sclerosis.</b></p> <p>3 Q. -- lichen sclerosis, correct?</p> <p>4 <b>A. That is correct.</b></p> <p>5 Q. And her pelvic pain is caused by or secondary</p> <p>6 to the Avaulta mesh in your opinion, correct?</p> <p>7 <b>A. Correct.</b></p> <p>8 Q. So explain to me just so I understand the</p> <p>9 difference in the two types of pain you're talking</p> <p>10 about?</p> <p>11 <b>A. You have to understand neuroanatomy.</b></p> <p>12 <b>Neuroanatomy is very logical. Nerves that are</b></p> <p>13 <b>irritated, you can follow them back to wherever they</b></p> <p>14 <b>are. Different nerves carry different stimuli, pain,</b></p> <p>15 <b>temperature differences. On the skin they are carried</b></p> <p>16 <b>by the dermatomes, which exit the back and wrap around,</b></p> <p>17 <b>okay. That is not evolved by Avaulta product. The</b></p> <p>18 <b>Avaulta product does not hit the skin dermatomes.</b></p> <p>19 <b>Avaulta will hit the deep nerves, the nerves</b></p> <p>20 <b>that are involved in the function of the bladder, a</b></p> <p>21 <b>sensation deep within the vagina. So based upon my</b></p> <p>22 <b>understanding of neuroanatomy and my education, they are</b></p> <p>23 <b>completely separate entities.</b></p> <p>24 Q. And do you have any studies or scientific</p> <p>25 literature that you can cite to me in support of what</p>	<p style="text-align: right;">Page 691</p> <p>1 vaginal tissues?</p> <p>2 <b>A. If the vagina were radiated during the healing</b></p> <p>3 <b>period, the first six-or-so weeks afterwards, that</b></p> <p>4 <b>possibly could play a role. If radiation is done</b></p> <p>5 <b>afterwards, there is no data to support impaired</b></p> <p>6 <b>healing.</b></p> <p>7 Q. She has -- Mrs. Bolyard has vaginal atrophy as</p> <p>8 well, correct? Did you see that in your review of her</p> <p>9 records?</p> <p>10 <b>A. I say moderately atrophic.</b></p> <p>11 Q. She's been on Premarin and Estrace for that</p> <p>12 condition, correct?</p> <p>13 <b>A. She's on Estrace. I don't know about vaginal</b></p> <p>14 <b>Premarin. I don't recall. I would have to, again, look</b></p> <p>15 <b>at the records to be specific. They're both vaginal</b></p> <p>16 <b>estrogens regardless.</b></p> <p>17 Q. Okay. This isn't really surprising seeing as</p> <p>18 Mrs. Bolyard was a 70-year-old woman at the time of the</p> <p>19 procedure?</p> <p>20 MS. GAYLE: Objection. Form.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. It wouldn't be unusual or atypical for a</p> <p>23 70-year-old woman to have vaginal atrophy?</p> <p>24 <b>A. It's not beyond -- it would be consistent.</b></p> <p>25 <b>It's not uncommon. I should put it that way.</b></p>
<p style="text-align: right;">Page 690</p> <p>1 you just said?</p> <p>2 <b>A. Grey's Anatomy.</b></p> <p>3 Q. Anything else?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A. Clemente's Anatomy.</b></p> <p>7 Q. Did you consider the fact that Mrs. Bolyard</p> <p>8 was diagnosed with lymphoma shortly after her mesh</p> <p>9 implant surgery and underwent radiation therapy? Could</p> <p>10 the radiation therapy be a potential cause for her</p> <p>11 problems or challenges with wound healing?</p> <p>12 <b>A. It depends where she got her -- it depends the</b></p> <p>13 <b>timing of the radiation and the location of the</b></p> <p>14 <b>radiation. I don't recall, off the top of my head,</b></p> <p>15 <b>where she received radiation.</b></p> <p>16 Q. And did you look at that when you reviewed the</p> <p>17 medical records in the case to see whether or not it</p> <p>18 would potentially have an impact on her delayed healing?</p> <p>19 <b>A. Yes, I did, and I just don't recall from the</b></p> <p>20 <b>records, so we'd need to look at that. Lymphoma, if</b></p> <p>21 <b>it's treated with radiation, usually is a pinpoint.</b></p> <p>22 <b>They are radiating a certain location of the body. So,</b></p> <p>23 <b>again, I would have to look, review the records to</b></p> <p>24 <b>refresh my memory.</b></p> <p>25 Q. Could radiation therapy have an impact on the</p>	<p style="text-align: right;">Page 692</p> <p>1 Q. You note, in your report, Doctor, that</p> <p>2 Mrs. Bolyard was experiencing urge incontinence,</p> <p>3 correct?</p> <p>4 <b>A. Yes.</b></p> <p>5 Q. Are you attributing her urge incontinence to</p> <p>6 the Bard products?</p> <p>7 <b>A. I cannot blame Bard fully for that condition.</b></p> <p>8 <b>That condition can occur de novo. It could be</b></p> <p>9 <b>exacerbated by the presence of the Bard product.</b></p> <p>10 Q. So I'm just trying to understand your opinion</p> <p>11 with respect to urge incontinence. You understand, from</p> <p>12 a review of the records, that that was a condition she</p> <p>13 had prior to the implant of the Bard products, correct?</p> <p>14 <b>A. Correct.</b></p> <p>15 Q. Do you have an opinion in this case that the</p> <p>16 Bard products had any impact, whatsoever, on</p> <p>17 Mrs. Bolyard's urge incontinence?</p> <p>18 <b>A. I would have to go back and look at my records</b></p> <p>19 <b>here as far as the severity. If she had preexisting</b></p> <p>20 <b>urge incontinence and the severity of that urge</b></p> <p>21 <b>incontinence did not change afterwards; however, if it</b></p> <p>22 <b>increased dramatically, then the blame could be placed</b></p> <p>23 <b>upon the Avaulta product because the dissection of the</b></p> <p>24 <b>vesicovaginal place -- space where the vesicovaginal</b></p> <p>25 <b>plexus is, which is responsible for bladder function.</b></p>

<p style="text-align: right;">Page 693</p> <p>1 Q. Sitting here today, do you have an opinion, to  2 a reasonable degree of medical certainty or probability,  3 that the Bard products played any role in Mrs. Bolyard's  4 development of urge incontinence?  5 MS. GAYLE: Objection. Form.  6 BY THE WITNESS:  7 A. I'm looking at my records to see if I  8 documented severity change. I don't -- I don't see that  9 in there. Overreactive bladder, urge incontinence is a  10 very, very common condition, especially in this age  11 group. Again, I do not see a comparison of before and  12 afterwards. We would have to look at the records and  13 talk to the patient to find out if there has been a  14 change. If there has been only a minimal change, I am  15 agreeable with stating that the Bard product had minimal  16 impact upon that.  17 Q. How about no impact? If there is no change  18 reflected in the records, how about agreeing with me  19 that the Bard product had no impact on her development  20 of urge incontinence?  21 MS. GAYLE: Objection. Form.  22 BY THE WITNESS:  23 A. If there has been no change or only minimal  24 change, I am acceptable with saying that the Bard had no  25 impact upon it right now. I don't know what happened on</p>	<p style="text-align: right;">Page 695</p> <p>1 <b>currently. I don't recall, off the top of my head, how</b>  2 <b>sexually active she was before. It is a potential</b>  3 <b>significant impact upon her quality of life.</b>  4 Q. Well, it's only significantly -- it's only a  5 potential significant impact if she was actually  6 engaging in sexual intercourse prior to the implant of  7 the Bard products, correct?  8 MS. GAYLE: Object to form.  9 BY THE WITNESS:  10 A. Again, I would have to refresh my memory and  11 look at the records as far as if she was sexually active  12 before. I don't recall.  13 Q. Do you remember, from your review of the  14 records or review of the deposition testimony, that  15 Mrs. Bolyard's husband had erectile dysfunction  16 diagnosed years before the implant surgery?  17 MS. GAYLE: Objection. Form. Mischaracterizes  18 testimony.  19 BY THE WITNESS:  20 A. Okay. Again, I'd have to look at that. I  21 have no reason to doubt it, but I would have to look at  22 the record and see what that says.  23 Q. Well, if her husband was already having  24 problems engaging in sexual intercourse, this would have  25 an effect, would it not, on your opinion about her</p>
<p style="text-align: right;">Page 694</p> <p>1 <b>down the road. But right now there's been no impact.</b>  2 Q. With respect to your opinion that the lack of  3 physical intimacy has already cost Mrs. Bolyard a major  4 component of her quality of life and similar to your  5 opinions in the other cases, you state that the  6 long-term impact on her quality of life is difficult to  7 accurately ascertain, but many studies have shown that  8 long-term negative impact leads to issues relating to  9 depression. And you hold that opinion with respect to  10 Mrs. Bolyard?  11 A. Yes. And, hopefully, we can avoid the  12 discussion we've had on the previous two, because it's  13 going to be the exact same.  14 Q. Yeah. I don't want to go over prior  15 discussion. So my only question on that point is, did  16 you consider the status of Mrs. Bolyard and her  17 husband's sexual activity in reaching that opinion prior  18 to the implant?  19 A. You mean her degree of sexual activity prior  20 to?  21 Q. Yeah. When you talk about the fact that she's  22 experiencing dyspareunia and that she can't have  23 physical intimacy and this is going to impact her  24 quality of life, correct?  25 A. Yeah. And I state that, that she's not</p>	<p style="text-align: right;">Page 696</p> <p>1 quality of life after the implant?  2 MS. GAYLE: Objection. Form.  3 BY MS. GEIST:  4 Q. Wouldn't you need to know to what extent the  5 couple was engaging in sexual intercourse as a married  6 couple?  7 A. That's why I stated I would need to see what  8 the records state as far as her preop sexual activity  9 level.  10 Q. Well, you've already rendered the opinion in  11 this case this lack of physical intimacy has cost her a  12 major component, she's unlikely to ever regain the  13 benefit of physical intimacy again, and that this impact  14 may have a long-term negative impact and potentially  15 depression, correct?  16 Don't you have to -- in order to render such  17 an opinion, Doctor, don't you need to know what the  18 status of her sexual relations with her husband was  19 prior to the implant surgery?  20 MS. GAYLE: Objection. Form.  21 BY THE WITNESS:  22 A. Well, I state it on page 3. It says, prior to  23 her surgery, Ms. Bolyard was sexually active. However,  24 because of her diagnosis of lichen sclerosis, she did  25 describe pain with intercourse at introitus with</p>

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<p style="text-align: right;">Page 697</p> <p><b>1 insertion, and we have a reference number there.</b></p> <p>2 Q. So what's your -- what's the support for your</p> <p>3 opinion that she was sexually active? Did you know that</p> <p>4 her husband had erectile dysfunction that was diagnosed</p> <p>5 prior to the implant?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p><b>8 A. Yes. But, also, as a urologist, I'm also</b></p> <p><b>9 aware people have different types of sex. So I'm just</b></p> <p><b>10 going off of what I've been told in my questioning of</b></p> <p><b>11 Mrs. Bolyard and comparing it, again, with her physical</b></p> <p><b>12 exam. The same thing we've gone down before in the</b></p> <p><b>13 other individuals.</b></p> <p>14 Q. Do you understand, from your review of</p> <p>15 Mrs. Bolyard's records, that she had depression prior to</p> <p>16 her surgery in 2010?</p> <p><b>17 A. I would have to refresh my memory off of the</b></p> <p><b>18 medical records.</b></p> <p>19 Q. Well, did you consider her preexisting</p> <p>20 condition of depression in reaching your opinions in</p> <p>21 this case?</p> <p><b>22 A. Yes. And those individuals who all have</b></p> <p><b>23 preexisting depression are probably at increased risk</b></p> <p><b>24 with further stressors of worsening that depression,</b></p> <p><b>25 more susceptible.</b></p>	<p style="text-align: right;">Page 699</p> <p>1 that her outcome would have been any different than it</p> <p>2 is here. And I assume your answer would be the same</p> <p>3 answer you gave me for Mrs. Alonso and Mrs. Wheeler; is</p> <p>4 that also fair?</p> <p><b>5 A. That -- I'm sorry. Yeah. My testimony would</b></p> <p><b>6 be consistent with -- consistent with the previous two.</b></p> <p>7 Q. In any of those three cases we just went over</p> <p>8 together -- Mrs. Alonso, Mrs. Wheeler, and</p> <p>9 Mrs. Bolyard -- did you review and observe any of the</p> <p>10 mesh that had been excised from any of these three</p> <p>11 plaintiffs?</p> <p><b>12 A. On one of the individuals, there is a Dr.</b></p> <p><b>13 Ickelov report who has photos, and I cannot recall which</b></p> <p><b>14 individual has those.</b></p> <p>15 Q. You didn't actually observe and do any</p> <p>16 analysis of the excised mesh in Mrs. --</p> <p><b>17 A. Wheeler.</b></p> <p>18 Q. -- Alonso, Wheeler or Bolyard's case; is that</p> <p>19 correct?</p> <p><b>20 A. I personally did not. I reviewed the slides</b></p> <p><b>21 and the photos on Ms. Wheeler that were provided by</b></p> <p><b>22 Dr. Ickelov.</b></p> <p>23 Q. So you didn't look at the actual mesh explants</p> <p>24 or the mesh incised from any of the three plaintiffs; is</p> <p>25 that correct?</p>
<p style="text-align: right;">Page 698</p> <p>1 Q. In Mrs. Bolyard's case, Dr. Elliott, would you</p> <p>2 agree with me that, if she had had a native tissue or an</p> <p>3 ASC procedure, she could have experienced the same</p> <p>4 issues that she's complaining of today?</p> <p><b>5 A. Okay. My testimony is going to be identical</b></p> <p><b>6 to the previous ones, which is much more detailed than</b></p> <p><b>7 I'll be able to do now.</b></p> <p>8 Q. And you know what? If just want to stick with</p> <p>9 your prior statements. And as long as you're telling me</p> <p>10 that your opinions here would be the same as you gave me</p> <p>11 for Mrs. Alonso and Mrs. Wheeler, I can agree to that</p> <p>12 and we can shortcut it.</p> <p><b>13 A. Okay.</b></p> <p>14 MS. GAYLE: And my objections would also be the</p> <p>15 same.</p> <p>16 MS. GEIST: That's fine.</p> <p>17 BY THE WITNESS:</p> <p><b>18 A. No. That would be -- I think I stated my</b></p> <p><b>19 opinion well on the previous testimony, and it will be</b></p> <p><b>20 the same as your line of questioning now. So I'm</b></p> <p><b>21 agreeable to that.</b></p> <p>22 Q. Okay. And then my other question that I asked</p> <p>23 you, with respect to Mrs. Alonso and Mrs. Wheeler, is</p> <p>24 the same for Mrs. Bolyard. Had she had a transvaginal</p> <p>25 mesh implanted from another manufacturer, you can't say</p>	<p style="text-align: right;">Page 700</p> <p><b>1 A. I did not personally hold that mesh or</b></p> <p><b>2 personally do studies on that mesh. I did read the</b></p> <p><b>3 report on Mrs. Wheeler by Dr. Ickelov and looked at the</b></p> <p><b>4 photos of that mesh.</b></p> <p>5 Q. Okay. And I assume -- are you deferring to</p> <p>6 any of the conclusions reached by Dr. Ickelov with</p> <p>7 respect to Mrs. Wheeler's pathology?</p> <p><b>8 A. Yes. He has had a very thorough, detailed</b></p> <p><b>9 write-up. I would defer to him on those issues.</b></p> <p>10 Q. Okay. He is a pathologist; is that right?</p> <p><b>11 A. Actually, his credentials I don't -- off the</b></p> <p><b>12 top of my head, I can't recall. He's involved in</b></p> <p><b>13 pathology. But, again, I -- I'd have to plead a little</b></p> <p><b>14 ignorance. I can't recall.</b></p> <p>15 Q. Okay. So you're deferring to whatever he has</p> <p>16 to say about the excised mesh of Mrs. Wheeler, correct?</p> <p><b>17 A. He has done microscopic evaluations on those.</b></p> <p><b>18 I will defer to his opinions on that specific patient.</b></p> <p>19 Q. And you haven't reviewed any of the excised</p> <p>20 mesh taken from Mrs. Alonso, Mrs. Wheeler, or</p> <p>21 Mrs. Bolyard to reach any conclusion with respect to</p> <p>22 degradation; is that correct?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p><b>25 A. No. That is incorrect. Specifically, on</b></p>

<p style="text-align: right;">Page 701</p> <p>1 Mrs. Wheeler, where there is documentation of  2 degradation, contraction, inflammatory process, I have  3 reviewed it and it is consistent with my physical exam  4 findings and my understanding of the available data out  5 there in manuscripts.  6 Q. You don't have any opinion with respect to  7 degradation for Mrs. Bolyard and Mrs. Alonso; is that  8 correct?  9 A. That is incorrect.  10 Q. Well, you didn't review any of the slides or  11 anything like that for the excised mesh in those two  12 cases, correct?  13 A. I did not personally examine those. However,  14 my physical exam, based upon my experience and knowledge  15 of the literature states that, when you have a firm,  16 gran- -- excuse me, not granulated -- nodule at the  17 level of the obturator foramen that is exquisitely  18 tender on exam, that is consistent with mesh degradation  19 caused by inflammation, inflammation causing pain.  20 Q. And do you hold that opinion in each one of  21 these three cases we just talked about?  22 A. Correct. My opinion would be consistent with  23 all three.  24 Q. And your opinion is based on the physical  25 exam; is that correct?</p>	<p style="text-align: right;">Page 703</p> <p>1 A. I am describing that from when I take out  2 these tissue, these meshes, I hold them in my hands, I  3 have our pathologist review them, but they are --  4 they're brittle, they crack, they're sharp, they can  5 poke you through the glove. You have to use very large  6 scissors, heavy-duty scissors to cut them out. To me,  7 that is clinical manifestations of degradation and the  8 cascade that happens from that.  9 Q. So I think we're just -- I don't want to have  10 the record be confused. You didn't actually hold any of  11 the excised mesh from any of these three plaintiffs  12 which we've just talked about, correct?  13 A. That is correct.  14 Q. Okay. So I want to focus on the three  15 plaintiffs, okay?  16 A. Okay.  17 Q. You didn't look at any of the mesh removed  18 from any of these women under a microscope or look at  19 them at any point in time, correct?  20 A. I -- well, with Ms. Wheeler, I looked at the  21 photographs and Dr. Ickelov's report. So, yes, I looked  22 at it. I did not personally look under a microscope at  23 them. Okay.  24 Q. Including for Mrs. Wheeler, correct?  25 A. Wheeler, only Wheeler.</p>
<p style="text-align: right;">Page 702</p> <p>1 A. Not just the physical exam. That's a very  2 good question. Not just the physical exam. I have to  3 correlate it with the available data that is out there,  4 Cobb, Klosterhalfen, others. There are many others  5 describing degradation of the tissues. Then correlating  6 that with my own surgical experience, even as of last  7 week of taking these things out, pulling them out,  8 they're brittle, they break, they're sharp, they're  9 painful, then correlating that with my physical exam I  10 do daily in my practice and correlating that with the  11 exams that I did on these three individuals.  12 Q. And when you're talking about degradation,  13 you're talking about that from a clinician's perspective  14 and not a biomaterials expert perspective; is that fair  15 to say?  16 MS. GAYLE: Objection. Form.  17 BY THE WITNESS:  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 704</p> <p>1 Q. Wait. Hold on. This is not -- this is not  2 clear to me at all, Doctor. So let's go one step at a  3 time so we have a clear record.  4 For Mrs. Alonso and Mrs. Wheeler and  5 Mrs. Bolyard, in any of those three cases, did you  6 actually visibly look at any of the excised mesh from  7 those three plaintiffs?  8 MS. GAYLE: Objection. Form.  9 BY THE WITNESS:  10 A. Again, just so we're clear, on Ms. Wheeler, I  11 have reviewed Dr. Ickelov's report, which includes in  12 there photographs of the specimens that have been taken  13 out of her.  14 Q. So you looked at photographs that were  15 included in Dr. Ickelov's report?  16 A. That is correct.  17 Q. For Mrs. Wheeler?  18 A. For just Mrs. Wheeler.  19 Q. Okay. You didn't look at photographs with  20 respect to the mesh excised from Mrs. Bolyard or  21 Mrs. Alonso, correct?  22 A. Correct.  23 Q. You didn't look at pathology slides for any of  24 the three plaintiffs, correct?  25 A. No. That's incorrect. I looked at the</p>



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<p style="text-align: right;">Page 705</p> <p>1 <b>pathology slides on Mrs. Wheeler that were included in</b>  2 <b>Dr. Ickelov's report.</b>  3 Q. The photographs?  4 <b>A. The photographs of the pathologic specimen.</b>  5 Q. Understood. But you didn't actually look at  6 the slides. You didn't have the slide in your hand and  7 look at the mesh under a microscope for Mrs. Wheeler,  8 correct?  9 <b>A. No. I only looked at a photograph of the -- a</b>  10 <b>representative photograph of the specimen. I did not</b>  11 <b>personally sit at a microscope with a glass side and</b>  12 <b>look at it.</b>  13 Q. Okay. Thank you. Have you ever done that?  14 Have you ever looked at excised mesh under a microscope?  15 <b>A. Yes.</b>  16 Q. Did you ever do that before you got involved  17 as an expert in the pelvic mesh litigation?  18 <b>A. Yes. In 2004, 2003, 2004, and then 2005 or</b>  19 <b>so, in my animal studies on the rabbits that we reviewed</b>  20 <b>yesterday.</b>  21 Q. Yes, and I remember those studies. So my  22 question was poor. Before you became involved in this  23 litigation as an expert for the plaintiffs, did you ever  24 look at excised mesh that had come from a woman's body  25 under a microscope?</p>	<p style="text-align: right;">Page 707</p> <p>1 Q. No. I'm not trying to. I'm just trying to  2 understand and I want to make sure the record is clear.  3 You've looked at photographs of slides that have been  4 reviewed by a pathologist or a biomaterials expert,  5 correct?  6 MS. GAYLE: Objection. Asked and answered.  7 BY THE WITNESS:  8 <b>A. Yes. Of my own personal patients that I have</b>  9 <b>excised mesh and mesh complications, as part of my</b>  10 <b>routine, I review the pathologic specimens provided to</b>  11 <b>me by my pathology team. So I review those as part of</b>  12 <b>our routine.</b>  13 Q. So when you say the pathological specimens,  14 are you talking about slides or are you talking about  15 photographs?  16 <b>A. Photographs of the pathologic specimen.</b>  17 Q. Got it. So you've never looked at actual  18 pathology slides?  19 <b>A. I have --</b>  20 MS. GAYLE: Objection. Form.  21 BY THE WITNESS:  22 <b>A. I have not sat down with a glass specimen</b>  23 <b>looking under a microscope on the individuals I</b>  24 <b>reviewed. I look at the photographic representative the</b>  25 <b>pathologist provides me.</b></p>
<p style="text-align: right;">Page 706</p> <p>1 <b>A. I have looked at the photograph of specimens</b>  2 <b>that my pathologists at my institution have provided for</b>  3 <b>the medical records on the ones that I have excised.</b>  4 Q. Okay. So the answer to my question is, no,  5 you, personally, Dr. Elliott, have not looked at excised  6 mesh under a microscope that came from a woman's body,  7 correct?  8 MS. GAYLE: Objection. Form.  9 BY THE WITNESS:  10 <b>A. I have personally examined mesh excised from</b>  11 <b>our animal studies on the rabbit, which are documented</b>  12 <b>in two different publications. I have not sat down with</b>  13 <b>a microscope and looked at the slide specimens of the</b>  14 <b>individuals I have taken out. I have looked at the</b>  15 <b>photographs, representative photographs my pathologists</b>  16 <b>have given me, on individuals I've excised.</b>  17 Q. Okay. So I think we're talk -- I think we're  18 saying the same thing. You never actually looked at  19 slides under a microscope of excised mesh that came from  20 women, correct?  21 MS. GAYLE: Objection. Form.  22 BY THE WITNESS:  23 <b>A. Yeah. I answered that, and I answered it</b>  24 <b>very, very carefully because you're limiting what --</b>  25 <b>what I just said.</b></p>	<p style="text-align: right;">Page 708</p> <p>1 Q. Okay. And the pathologist also, I assume,  2 provides you with a pathology report?  3 <b>A. Usually, yes. Yes, he does.</b>  4 Q. That's what a pathologist does? That's their  5 job?  6 <b>A. That is correct.</b>  7 Q. Okay. Back to Mrs. Bolyard's report,  8 specifically, Doctor, for a moment, on page 8 of this  9 report, the second paragraph --  10 <b>A. Yes.</b>  11 Q. -- this is the same paragraph that I referred  12 to you when we started your deposition today. Do you  13 remember that?  14 <b>A. I don't.</b>  15 Q. I realize it was some time ago.  16 <b>A. I don't remember that now.</b>  17 Q. Okay. This -- this paragraph, on page 8 of  18 Mrs. Bolyard's report, starts out by saying, Set out in  19 my general causation expert report, several  20 characteristics of the Marlex polypropylene mesh  21 rendering inherently unsafe for use in Ms. Bolyard. And  22 then you provide five specific reasons why you opine  23 that the characteristics of the Marlex polypropylene  24 mesh render it unsafe for use in Mrs. Bolyard?  25 <b>A. Correct.</b></p>

<p style="text-align: right;">Page 709</p> <p>1 Q. And this is the same paragraph that's in</p> <p>2 Mrs. Alonso's report and Mrs. Wheeler's report, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And then, in the pages that we went over with</p> <p>5 some frequency earlier, pages 8 to 11, these are all of</p> <p>6 the things that you say should have gone into the IFU</p> <p>7 for the Avaulta products, correct?</p> <p>8 A. That is correct, and my previous testimony</p> <p>9 correlates with this as well.</p> <p>10 Q. And, in this section, you're basing your</p> <p>11 opinion on what you think Bard knew and understood about</p> <p>12 these risks based on the Bard internal documents that</p> <p>13 you've included in your reliance materials?</p> <p>14 A. Not just the internal documents, but also the</p> <p>15 medical literature that was readily available.</p> <p>16 Q. And you think -- well, let me ask you. Do you</p> <p>17 believe that Bard intended to omit this information from</p> <p>18 the medical community? Is that your opinion based on</p> <p>19 your review of the internal Bard documents?</p> <p>20 MS. GAYLE: Objection. Mischaracterizes his</p> <p>21 opinions.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I cannot -- I can only speculate what the</p> <p>24 company was doing with this data in withholding it. I</p> <p>25 can only have a theory.</p>	<p style="text-align: right;">Page 711</p> <p>1 MS. GAYLE: Objection. Form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. It would depend upon what risk we're talking</p> <p>4 about or what complication we're talking about.</p> <p>5 Ignorance of risks and ignorance of literature is not an</p> <p>6 excuse. So I can't give a carte blanche acceptance of</p> <p>7 your statement. We'd have to go point by point.</p> <p>8 Q. Well if a medical device company such as Bard</p> <p>9 believed that there was no health consequence or risk,</p> <p>10 it would be misleading to put that information on a</p> <p>11 label. Would you agree with me on that?</p> <p>12 MS. GAYLE: Objection. Form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I would want to see what that risk is and see</p> <p>15 if I agree with the company that it is truly not a risk.</p> <p>16 Q. Well, you have, in all of these expert reports</p> <p>17 relating to the Marlex polypropylene mesh, you state, in</p> <p>18 all of your reports, that Bard utilizes nonmedical grade</p> <p>19 polypropylene, the supplier of which has forbidden its</p> <p>20 use in humans because of its known degradation</p> <p>21 characteristics. And then you say, in your IFU section,</p> <p>22 that Bard should have included this information in the</p> <p>23 IFU and told physicians about this.</p> <p>24 Are those -- is that your opinion in this</p> <p>25 case?</p>
<p style="text-align: right;">Page 710</p> <p>1 Q. Are you inferring Bard's intent from your</p> <p>2 review of the records that you were provided in this</p> <p>3 litigation?</p> <p>4 MS. GAYLE: Objection. Question calls for a legal</p> <p>5 conclusion.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yeah. I could only provide a theory of why</p> <p>8 this was not provided in the form that I feel is</p> <p>9 acceptable. That question would be best answered by the</p> <p>10 Bard personnel.</p> <p>11 Q. In the context of our discussion about all of</p> <p>12 these risks that you think should be in the IFU, you</p> <p>13 believe that a medical device company should include all</p> <p>14 risks of which it is aware in the IFU; is that a fair</p> <p>15 summary?</p> <p>16 MS. GAYLE: Objection. Form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I believe that the requirements established</p> <p>19 are that the company is required to provide all known</p> <p>20 risks regardless of the severity.</p> <p>21 Q. All right. So would you agree with me that,</p> <p>22 if a medical device company is not aware of a risk, a</p> <p>23 risk to an individual patient's health and well-being,</p> <p>24 that they would not need to include that information in</p> <p>25 the IFU?</p>	<p style="text-align: right;">Page 712</p> <p>1 A. Yes, as stated.</p> <p>2 Q. And my question to you is, if Bard believed</p> <p>3 that this was a hypothetical and not a real risk</p> <p>4 relating to the Marlex polypropylene, should it have</p> <p>5 included that information in the IFU?</p> <p>6 MS. GAYLE: Objection. Calls for speculation.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I think they owed -- they had a right. Excuse</p> <p>9 me. The doctors and the patients, the doctor, who is</p> <p>10 the implanter, and the woman that this is going to go in</p> <p>11 the body, they are the ones who should be choosing that,</p> <p>12 not the company. And if they had -- if they felt there</p> <p>13 was no risk to this, then they should have done the</p> <p>14 studies to show there was no risk.</p> <p>15 Q. Well, you read the testimony from individuals</p> <p>16 at Bard on this issue, the use of the Marlex</p> <p>17 polypropylene, did you not?</p> <p>18 A. I've read many depositions, yes.</p> <p>19 Q. And so you read Bard's testimony that the</p> <p>20 company did not believe that there was any medical or</p> <p>21 scientific reason for the medical application caution in</p> <p>22 the MSDS sheet for the Marlex polypropylene. Did you</p> <p>23 read that?</p> <p>24 MS. GAYLE: Objection. Form. I believe you all</p> <p>25 discussed the MSDS yesterday.</p>

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<p style="text-align: right;">Page 713</p> <p>1 MS. GEIST: We did not.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. I have to go back. The actual manufacturer,</b></p> <p>4 <b>Phillips Sumika, came out with that warning. I would</b></p> <p>5 <b>assume that they are going to be the authority on this</b></p> <p>6 <b>product. They are the manufacturer of the product.</b></p> <p>7 <b>They issued the warning for a reason.</b></p> <p>8 Q. You say Phillips Sumika is the manufacturer of</p> <p>9 the product?</p> <p>10 <b>A. Of the -- the Marlex substrate or the</b></p> <p>11 <b>polypropylene substrate.</b></p> <p>12 Q. You understand that that MSDS sheet that</p> <p>13 you're referring to is not an MSDS sheet for the final</p> <p>14 Bard Avaulta product, don't you?</p> <p>15 MS. GAYLE: Objection. Form.</p> <p>16 BY THE WITNESS:</p> <p>17 <b>A. It is a warning for the basic fundamental</b></p> <p>18 <b>building blocks of the mesh that's going to go into</b></p> <p>19 <b>women.</b></p> <p>20 Q. It -- it relates to the raw material, the</p> <p>21 polypropylene pellet; is that a fair summary?</p> <p>22 MS. GAYLE: Continuing objection.</p> <p>23 BY THE WITNESS:</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 715</p> <p>1 <b>A. Yeah. He was representing the company. The</b></p> <p>2 <b>30(b)(6), I've never heard of that specific designation.</b></p> <p>3 <b>I have no reason to disagree with that.</b></p> <p>4 Q. Did anybody ever tell you what that means to</p> <p>5 be a 30(b)(6) witness?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p>8 <b>A. I don't -- I don't recall being told that.</b></p> <p>9 Q. Well, assume with me, Doctor, and I'll make</p> <p>10 this representation to you, that that means that that</p> <p>11 person is charged with speaking for the company on a</p> <p>12 particular topic and they need to be informed about that</p> <p>13 particular topic.</p> <p>14 <b>A. Okay.</b></p> <p>15 Q. Okay. So assuming -- strike that.</p> <p>16 Assuming that the Phillips Marlex -- I'm</p> <p>17 sorry, the Phillips Sumika representative was a 30(b)(6)</p> <p>18 witness, somebody charged with speaking about that</p> <p>19 issue, why the medical application caution language was</p> <p>20 in the MSDS, assuming all of that, didn't that</p> <p>21 individual testify that he was not aware of any medical</p> <p>22 or scientific reason for the inclusion of that language</p> <p>23 in the MSDS sheet?</p> <p>24 MS. GAYLE: Continuing objection as to the form and</p> <p>25 to this entire line of questioning. You had your chance</p>
<p style="text-align: right;">Page 714</p> <p>1 <b>A. That is just what I stated. It's the</b></p> <p>2 <b>substrate, yes.</b></p> <p>3 Q. And did you read the testimony from Bard</p> <p>4 concerning why they believed that that was not a risk</p> <p>5 that needed to be included in the IFU or communicated to</p> <p>6 doctors? Did you review that testimony as I believe I</p> <p>7 saw in your reliance list?</p> <p>8 <b>A. Yes. No. I've read it. I can't recall all</b></p> <p>9 <b>of the details off the top of my head. I also read the</b></p> <p>10 <b>deposition by the Phillips -- or Zumika (sic), whatever</b></p> <p>11 <b>his name is, it starts with a Z. I've read his warning</b></p> <p>12 <b>on it. And he says this is a warning.</b></p> <p>13 Q. You're referring to the testimony of Frank</p> <p>14 Zakrzewski -- and we can check the spelling after your</p> <p>15 deposition -- the representatives from the Phillips</p> <p>16 Sumika company?</p> <p>17 <b>A. The salesperson that was test- -- that</b></p> <p>18 <b>testified, yes.</b></p> <p>19 Q. And you were provided with that testimony,</p> <p>20 correct?</p> <p>21 <b>A. Correct.</b></p> <p>22 Q. And you just said to me he is a salesperson.</p> <p>23 Did you understand, when you read it, that he was what</p> <p>24 we call a 30(b)(6) witness or a corporate representative</p> <p>25 on that issue?</p>	<p style="text-align: right;">Page 716</p> <p>1 yesterday. Y'all talked about an MSDS yesterday and</p> <p>2 this Marlex, and I think that this is going over ground</p> <p>3 that you already should have covered yesterday.</p> <p>4 MS. GEIST: Well, and I appreciate that objection,</p> <p>5 but we didn't talk about the MSDS at all yesterday. And</p> <p>6 it is contained in each one of these case-specific</p> <p>7 reports and as part of Dr. Elliott's opinions as to what</p> <p>8 should have been included and provided in the three</p> <p>9 implanting physicians in these three cases. So I'm</p> <p>10 entitled to explore it.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. I'll make the statement that, again, I'd have</b></p> <p>13 <b>to -- I'm going off of memory, that he made the</b></p> <p>14 <b>statement that he was not aware of studies or whatever.</b></p> <p>15 <b>That does not mean that he was condoning it. And then</b></p> <p>16 <b>he came back on deposition, page 205, lines 7 through 8,</b></p> <p>17 <b>I view it as a warning that should be taken seriously.</b></p> <p>18 Q. Do you have the entirety of the testimony</p> <p>19 there?</p> <p>20 <b>A. I don't have the entirety of the testimony</b></p> <p>21 <b>here.</b></p> <p>22 Q. I think I saw, in your reliance list in these</p> <p>23 cases, that you also reviewed prior versions of the</p> <p>24 Phillips Sumika MSDS sheet, earlier versions?</p> <p>25 <b>A. I'm -- I guess I'm not following. I've</b></p>

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<p style="text-align: right;">Page 717</p> <p><b>1 reviewed multiple different records, an earlier record.</b></p> <p>2 Q. I thought I saw in your reliance list, Doctor,</p> <p>3 that you had reviewed a number of different versions of</p> <p>4 the MSDS sheet; am I right about that?</p> <p><b>5 A. I've reviewed thousands of pages of documents.</b></p> <p><b>6 I can't -- I can't recall.</b></p> <p>7 Q. Okay. And I don't mean to be tricky. I'll</p> <p>8 just show them to you so we all are on the same page.</p> <p>9 MS. GEIST: Madame Court Reporter, what number am I</p> <p>10 up to?</p> <p>11 THE REPORTER: 36.</p> <p>12 (Elliott Exhibit Nos. 36, 37 &amp; 38</p> <p>13 were marked for identification.)</p> <p>14 MS. GEIST: Counsel, would you like copies of</p> <p>15 these?</p> <p>16 BY MS. GEIST:</p> <p>17 Q. Doctor, I'm handing you what I've marked to</p> <p>18 your deposition as Exhibits 36, 37, and 38. And, for</p> <p>19 the record, these are copies of the Phillips Sumika</p> <p>20 Materials Safety Data Sheet, or MSDS. Exhibit 36 is the</p> <p>21 2007 version, Exhibit 37 is the 1993 version, and</p> <p>22 Exhibit 38 is the 1997 -- I'm sorry, 1997 version. And,</p> <p>23 Counsel, I'll give you copies in just a second. Do</p> <p>24 these look familiar to you?</p> <p>25 MS. GAYLE: Hold on, Counsel. I'm not letting him</p>	<p style="text-align: right;">Page 719</p> <p>1 or tissue?</p> <p>2 MS. GAYLE: Counsel, would you point him to</p> <p>3 where --</p> <p>4 BY THE WITNESS:</p> <p><b>5 A. That's what I'm trying to find. That's all.</b></p> <p>6 Q. Yeah. I'm trying to help you, Doctor. If you</p> <p>7 want to look at me down here, do you see it says Medical</p> <p>8 Application Caution, right here? (Indicating.)</p> <p><b>9 A. Oh, here it is.</b></p> <p>10 Q. There you go.</p> <p><b>11 A. Okay. Yes. Yes.</b></p> <p>12 Q. That's what you're talking about in your</p> <p>13 expert reports, right?</p> <p><b>14 A. Correct.</b></p> <p>15 Q. And you're saying -- well, you tell me. Are</p> <p>16 you saying, based on this, that Bard was told that this</p> <p>17 material should not be used in a permanent -- in a</p> <p>18 permanent implantation in a human body; and because Bard</p> <p>19 knew about this, they should have told doctors about</p> <p>20 this information. Is that your opinion?</p> <p><b>21 A. That's my opinion. I can't speak for Bard,</b></p> <p><b>22 but I can state that Phillips Sumika warned Bard of</b></p> <p><b>23 this.</b></p> <p>24 Q. And my question to you is, if Bard believed</p> <p>25 that there was no medical or scientific reason for that</p>
<p style="text-align: right;">Page 718</p> <p>1 look at them yet until I look at them.</p> <p>2 MS. GEIST: Sure. No. I have your copies here.</p> <p>3 Sorry, I'm a little slow. It's the end of the day.</p> <p>4 MS. GAYLE: I'm ready for my copies.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. Do you -- do you have those three MSDS sheets</p> <p>7 in front of you?</p> <p><b>8 A. Yes, I do.</b></p> <p>9 Q. Dr. Elliott?</p> <p><b>10 A. Yes, I do.</b></p> <p>11 Q. Okay. Now, the one that you discussed, in</p> <p>12 each of your case-specific reports of Ms. Alonso,</p> <p>13 Mrs. Wheeler, and Mrs. Bolyard is the first one that</p> <p>14 I've marked as an exhibit to your deposition. This is</p> <p>15 the one that contains the medical application caution</p> <p>16 language, correct, the 2007 version?</p> <p><b>17 A. I don't see the language I'm familiar with.</b></p> <p>18 Q. Doctor, if you have the -- yeah, that's the</p> <p>19 right exhibit in front of you, the 2007 version. The</p> <p>20 language that you're talking about in your expert report</p> <p>21 is the medical application caution language, is it not?</p> <p>22 And, it says, on this exhibit, Do not use this Chevron</p> <p>23 Phillips Chemical Company material in medical</p> <p>24 applications involving permanent implantation in the</p> <p>25 human body or permanent contact with human body fluids</p>	<p style="text-align: right;">Page 720</p> <p>1 medical application caution language and it was included</p> <p>2 there for another reason that had nothing to do with</p> <p>3 patient safety, would Bard have any obligation to put</p> <p>4 that information in the IFU?</p> <p>5 MS. GAYLE: Object to form.</p> <p>6 BY THE WITNESS:</p> <p><b>7 A. I don't believe that is Bard's call to make.</b></p> <p><b>8 If this warning is here, the doctor and the patient need</b></p> <p><b>9 to be warned. And if Bard felt there was no problems</b></p> <p><b>10 with this, then I don't see why they were trying to hide</b></p> <p><b>11 it up on those series of e-mails. It's very</b></p> <p><b>12 well-documented where they're trying to hide it. That</b></p> <p><b>13 does not seem like what an upfront company would do.</b></p> <p>14 Q. Well, let's look at it. We just looked at the</p> <p>15 2007 version together, correct? That medical</p> <p>16 application caution, I just read it to you, right?</p> <p><b>17 A. Correct.</b></p> <p>18 Q. And underneath it, it says, Do not use this</p> <p>19 Chevron Phillips Chemical Company material medical</p> <p>20 applications -- and I'm going to skip a little bit --</p> <p>21 and then, it says, Unless the material has been provided</p> <p>22 directly from Chevron Phillips Chemical Company under an</p> <p>23 agreement which expressly acknowledges the contemplated</p> <p>24 use?</p> <p>25 MS. GAYLE: Objection. Form.</p>

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<p style="text-align: right;">Page 721</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Do you see that information there, Doctor?</p> <p>3 <b>A. Yes. That's what it states.</b></p> <p>4 Q. Did you review any materials or any</p> <p>5 information relating to Chevron Phillips entering into</p> <p>6 contracts with other medical device companies</p> <p>7 specifically for the use of this material in</p> <p>8 transvaginal mesh products?</p> <p>9 MS. GAYLE: Objection. Form. And objection,</p> <p>10 assumes facts not in evidence.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. I've heard of it with Boston Scientific.</b></p> <p>13 Q. So you're aware that Boston Scientific</p> <p>14 actually entered into a contract with the Phillips</p> <p>15 Sumika Company for this very same grade of Marlex</p> <p>16 polypropylene to use in their transvaginal products,</p> <p>17 transvaginal mesh products?</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 723</p> <p>1 MS. GAYLE: Objection. Form.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A. He stated he was unaware, but that does not</b></p> <p>4 <b>mean there is no data out there proving -- or there is</b></p> <p>5 <b>data out there proving it's not an issue. He was</b></p> <p>6 <b>unaware of anything.</b></p> <p>7 Q. Now, there is no citation to any medical study</p> <p>8 or literature supporting this application in the MSDS</p> <p>9 sheet itself, correct?</p> <p>10 MS. GAYLE: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. No. That would be best answered by a Phillips</b></p> <p>13 <b>Sumika representative, which we have. He says, I view</b></p> <p>14 <b>it as a warning. It should be taken seriously.</b></p> <p>15 Q. Have you ever seen any study looking</p> <p>16 specifically at the Phillips Sumika Marlex polypropylene</p> <p>17 and concluding that there was a medical or scientific</p> <p>18 reason that it should not be implanted in the human</p> <p>19 body? Have you ever seen any such study?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A. I don't recall with this specific grade of</b></p> <p>23 <b>polypropylene Marlex. I don't recall ever seeing a</b></p> <p>24 <b>study showing that it was safe.</b></p> <p>25 Q. Well, did you wonder why the Phillips Sumika</p>
<p style="text-align: right;">Page 722</p> <p>1 <b>A. I cannot -- I cannot testify to that. I have</b></p> <p>2 <b>not seen those records. I would like to see those</b></p> <p>3 <b>records and correlate to that. But that still does not</b></p> <p>4 <b>correlate. Just because Boston Scientific doesn't do</b></p> <p>5 <b>it, doesn't mean Bard should do it. And they had this</b></p> <p>6 <b>language here, and this does not excuse it.</b></p> <p>7 Q. Well, I'll show it to you in a minute. But my</p> <p>8 question is, do you think that, if the Phillips Sumika</p> <p>9 Company really believed that there was any safety issue</p> <p>10 relating to the implant of the Marlex polypropylene in</p> <p>11 the human body, that they would be providing it to</p> <p>12 Boston Scientific knowing full well what Boston</p> <p>13 Scientific intended to do with the material?</p> <p>14 MS. GAYLE: Objection, form and calls for</p> <p>15 speculation.</p> <p>16 BY THE WITNESS:</p> <p>17 <b>A. I cannot speak for the interaction with Boston</b></p> <p>18 <b>Scientific. We'd have to review all of those records.</b></p> <p>19 <b>All I can state is what Frank Zakrzewski said. I view</b></p> <p>20 <b>it as a warning. It should be taken seriously.</b></p> <p>21 Q. He also said, did he not, that he was unaware</p> <p>22 of any medical or scientific reason for the inclusion of</p> <p>23 this new language -- and this is what I want you to</p> <p>24 focus on -- the inclusion of this new language in the</p> <p>25 MSDS sheet? Didn't he also say that?</p>	<p style="text-align: right;">Page 724</p> <p>1 Company added this medical application caution language</p> <p>2 to the MSDS sheet?</p> <p>3 MS. GAYLE: Objection. Form and argumentative.</p> <p>4 Move to strike.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A. The company, an oil company, issued this</b></p> <p>7 <b>warning that their representative, who you've said is</b></p> <p>8 <b>their official representative, he said, I view it as a</b></p> <p>9 <b>warning. It should be taken seriously. So who do you</b></p> <p>10 <b>want me to believe? You want me to strike Zakrzewski's</b></p> <p>11 <b>statements. I mean, he states it. It's in here.</b></p> <p>12 <b>Patients need to know that. Doctors need to know it.</b></p> <p>13 Q. Now, look with me, if you would, at the</p> <p>14 earlier versions of the MSDS sheets for the same</p> <p>15 material. And as we look at this, let me ask you this</p> <p>16 question. Were you aware of how many years Bard had</p> <p>17 been using this same polypropylene grade, the Marlex</p> <p>18 polypropylene grade, in its mesh products?</p> <p>19 MS. GAYLE: Objection. Form.</p> <p>20 BY THE WITNESS:</p> <p>21 <b>A. First of all, I have no evidence that this is</b></p> <p>22 <b>the same grade. There are multiple different grades, I</b></p> <p>23 <b>believe, in the 30s, different grades. All I know is</b></p> <p>24 <b>HG6030-01 is the one referenced here. So I would want</b></p> <p>25 <b>to see studies specifically with that grade stating it</b></p>



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<p style="text-align: right;">Page 725</p> <p><b>1 is safe coming from the company, and I don't see it. I</b></p> <p><b>2 never saw that.</b></p> <p>3 Q. Now, if you look at the 1993 version of the</p> <p>4 MSDS sheet, do you have that in front of you, Doctor?</p> <p><b>5 A. Yes, I do.</b></p> <p>6 Q. There is no medical application caution</p> <p>7 language in that MSDS sheet?</p> <p><b>8 A. Okay. I would have to review through the</b></p> <p><b>9 whole record. And, again, I have no idea if this is</b></p> <p><b>10 pertaining to this specific grade.</b></p> <p>11 Q. I thought you looked at these materials</p> <p>12 because they were on your reliance sheet. Have you not</p> <p>13 seen these before?</p> <p>14 MS. GAYLE: Objection. Form. Argumentative. Move</p> <p>15 to strike statement of counsel.</p> <p>16 BY THE WITNESS:</p> <p><b>17 A. No. I reviewed these, and I just stated that</b></p> <p><b>18 I saw nothing in here to say that that is the exact same</b></p> <p><b>19 grade that is discussed in the 2007 document.</b></p> <p>20 Q. Are you disputing that it's the same grade or</p> <p>21 you just don't know?</p> <p>22 MS. GAYLE: Objection.</p> <p><b>23 THE WITNESS: I'm stating --</b></p> <p>24 MS. GAYLE: Move to strike.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 727</p> <p>1 BY THE WITNESS:</p> <p><b>2 A. No. I fully understand. And I fully</b></p> <p><b>3 understand. And look at this, and, perhaps, this should</b></p> <p><b>4 be addressed to the jury. Let them read this and ask</b></p> <p><b>5 the women would you want to know this. I see 2007 the</b></p> <p><b>6 specific grade that's implanted in women with warnings.</b></p> <p><b>7 You then show me a document from 1993. I don't know</b></p> <p><b>8 what the laws are. I don't know what the grade of this</b></p> <p><b>9 is. I don't know if it's the same grades we're talking</b></p> <p><b>10 about now. There is too much data that I don't know.</b></p> <p>11 Q. Does it -- on each of these three versions of</p> <p>12 the MSDS sheet, doesn't it say, Marlex polypropylene,</p> <p>13 all grades?</p> <p>14 MS. GAYLE: Object. Form.</p> <p>15 BY THE WITNESS:</p> <p><b>16 A. Yes. All grades in 1993 does not mean all</b></p> <p><b>17 grades in 2007.</b></p> <p>18 Q. Why not? It says all grades on this sheet?</p> <p><b>19 A. In 1993, if we say all Ford cars and in 1997</b></p> <p><b>20 there are different types of cars around, so that does</b></p> <p><b>21 not correlate. All grades, new warning. Perhaps, the</b></p> <p><b>22 company has come up and found there are problems with</b></p> <p><b>23 this.</b></p> <p>24 Q. Perhaps, or perhaps the company wanted to</p> <p>25 limit its own liability and ensure that they were not</p>
<p style="text-align: right;">Page 726</p> <p><b>1 A. I'm stating I'd want to see the data that the</b></p> <p><b>2 HGX030-01 has been proven safe and accepted by the</b></p> <p><b>3 company for Bard to use in implantation of women.</b></p> <p>4 Q. If you flip through the 1993 version of the</p> <p>5 MSDS sheet, can you agree with me there is no medical</p> <p>6 application caution language anywhere in the document?</p> <p><b>7 A. Well, I see they have other health effects,</b></p> <p><b>8 long-term exposure. The dust concentration can cause</b></p> <p><b>9 non-debilitating lung changes.</b></p> <p>10 Q. Right. Do you understand -- let me back up</p> <p>11 for a second, Dr. Elliott. Do you understand what an</p> <p>12 MSDS -- MSDS sheet is?</p> <p><b>13 A. Yes. Yeah. It's the, you know, medical</b></p> <p><b>14 device or Medical Safety Data Sheet, and this is your --</b></p> <p><b>15 you're showing me something from 1993, a long time ago,</b></p> <p><b>16 and then you show me 2007 where they're making a</b></p> <p><b>17 warning. Warnings change.</b></p> <p>18 Q. Well, it's not -- this has nothing to do with</p> <p>19 a medical device, does it? This has to do with a</p> <p>20 polypropylene pellet, a raw material that undergoes a</p> <p>21 number of manufacturing processes before it is woven</p> <p>22 into what ultimately becomes the Bard Avaulta mesh; do</p> <p>23 you understand that?</p> <p>24 MS. GAYLE: Move to strike. Objection. Form.</p> <p>25 Subject to that, you can answer, if you can.</p>	<p style="text-align: right;">Page 728</p> <p>1 getting embroiled in a product liability, personal</p> <p>2 injury lawsuit; isn't that a possibility?</p> <p>3 MS. GAYLE: Object. Move to strike. Object,</p> <p>4 argumentative.</p> <p>5 BY THE WITNESS:</p> <p><b>6 A. That sounds like a responsible company. And</b></p> <p><b>7 that's when it gets scary, if an oil company of all</b></p> <p><b>8 places is being more responsible on a product that goes</b></p> <p><b>9 in a human body.</b></p> <p>10 Q. Do you think their own concern about their</p> <p>11 liability equates with responsibility? Is that what</p> <p>12 you're telling me?</p> <p>13 MS. GAYLE: Move to strike. Objection. Form.</p> <p>14 Argumentative.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. And then how are they responsible if they sold</p> <p>17 this product, the Marlex polypropylene product, to</p> <p>18 another medical device company, Boston Scientific,</p> <p>19 knowing that Boston Scientific was going to use it in</p> <p>20 their pelvic mesh product to treat prolapse?</p> <p>21 MS. GAYLE: Move to strike. Objection,</p> <p>22 argumentative.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. Isn't that inconsistent? I mean, if Phillips</p> <p>25 Sumika sold the same grade of polypropylene to Boston</p>

<p style="text-align: right;">Page 729</p> <p>1 Scientific, isn't that inconsistent with their not 2 selling it to Bard? 3 MS. GAYLE: Objection, form. Objection, 4 argumentative, and move to strike. 5 BY THE WITNESS: 6 <b>A. I have seen no records from Boston Scientific</b> 7 <b>to correlate that this is the same grade. That would be</b> 8 <b>helpful. I have seen no records from any deposition to</b> 9 <b>say -- saying it's safe. All I have is records saying</b> 10 <b>it's dangerous. I'm saying that the woman has the right</b> 11 <b>to know this is going in her body and a company is</b> 12 <b>warning her about it.</b> 13 Q. All right. I'll show you one more document, 14 Doctor, and then I think that will end our discussion on 15 the MSDS topic. And I'm up to exhibit what? 16 THE REPORTER: 39. 17 MS. GEIST: 39. 18 (Elliott Deposition Exhibit No. 39 19 was marked for identification.) 20 BY MS. GEIST: 21 Q. Doctor, here is Exhibit 39. You've asked me a 22 couple of times to see this information. So my question 23 to you is, have you ever seen the information I've just 24 handed you for - which is marked as Exhibit 39? 25 <b>A. I don't recall if this is what I reviewed</b></p>	<p style="text-align: right;">Page 731</p> <p>1 answer. 2 MS. GEIST: Well, this is the last document I'm 3 going to show him on the issue. We did not talk about 4 the MSDS issue at all during his deposition yesterday. 5 He puts front and center this issue, the nonmedical 6 grade polypropylene, in each and every one of his 7 case-specific reports. And he also discusses it in 8 terms of what he expected Bard to put in the IFU. And 9 it is not my fault that this is included in each and 10 every one of his specific causation reports. 11 MS. GAYLE: It's incorporated -- 12 MS. GEIST: Now, I am -- and I am entitled to 13 explore whatever information he puts in his 14 case-specific reports. 15 MS. GAYLE: It is incorporated into the 16 case-specific reports from his general report, and it's 17 gone over ad nauseam in his general report. And so we 18 have our two different positions on it. And I'll let 19 you go a little bit on this Exhibit 39, but not -- not 20 long. And then if you go too much further, I'm going to 21 instruct him not to answer. 22 MS. GEIST: Well, that's fine. I already told you 23 I only plan on showing him one exhibit. I don't really 24 think either one of us believes that Dr. Elliott's 25 opinions are going to be changed by what I have to show</p>
<p style="text-align: right;">Page 730</p> <p>1 <b>before Pinnacle. And how is this not on the general</b> 2 <b>liability? I don't understand this. We went over this</b> 3 <b>yesterday. You wasted time yesterday. Now we're</b> 4 <b>talking about this. So let's get into it.</b> 5 MS. GAYLE: No, Doctor. I believe that this is 6 general liability. You guys talked about this stuff 7 yesterday. You went over this. 8 MS. GEIST: No, we did not. We did not talk about 9 MSDS, whatsoever. 10 MS. GAYLE: Counsel, it's in his general report. 11 And, Doctor, will you step out of the room, please? 12 (Exit the witness.) 13 MS. GAYLE: Counsel, it's our position that this is 14 in his general report and you were given the opportunity 15 yesterday to answer questions and ask questions related 16 to his general report. And the fact that you're 17 rehashing these general statements today we think is 18 beyond the scope of what he's here for today. 19 Today he's here about case specifics. You're 20 not asking questions specific to those three individuals 21 and how it relates to his opinion. You're showing him a 22 document now, Exhibit 39, that even has to do with 23 Boston Scientific. Again, this is general matter, and 24 I'm -- I'm hesitant to do it, but I'm nearing the point 25 that I think I'm going to have to instruct him not to</p>	<p style="text-align: right;">Page 732</p> <p>1 him, but we're going to explore the issue. I think it's 2 only fair that he gets this full picture. 3 MS. GAYLE: Okay. Can you go off the record for a 4 moment so I can go get him? 5 VIDEO TECHNICIAN: We're off the record. The time 6 is 3:03 p.m. 7 (A recess was had.) 8 (Enter the witness.) 9 VIDEO TECHNICIAN: We are back on the record. The 10 time is 3:09 p.m. 11 BY MS. GEIST: 12 Q. Doctor, you have Exhibit 39 in front of you? 13 <b>A. Correct.</b> 14 Q. Were you provided with this previously? 15 <b>A. I don't recall seeing this before.</b> 16 Q. Okay. If you go with me to look to the actual 17 third page of the document, it actually says, page 5, on 18 the top left corner. Do you see that? 19 <b>A. I'm on the third page. I'm on the third page.</b> 20 <b>I don't see a page 5 anywhere, but I'm on the third page</b> 21 <b>of it.</b> 22 Q. Okay. Well, do you -- please take a look at 23 the front page of the document before we get to page 5. 24 I just want you to see that, in June of 2008, FDA asked 25 Boston Scientific about the MSDS they used for Marlex</p>

<p style="text-align: right;">Page 733</p> <p>1 polypropylene resin purchased from Phillips Sumika.</p> <p>2 <b>A. Okay. I've never seen it. It's a 23-page</b></p> <p>3 <b>document, which I've never seen before, which,</b></p> <p>4 <b>obviously, this is a very important document. And so, I</b></p> <p>5 <b>mean, to be fair, I need to be able to review this.</b></p> <p>6 Q. Understood. And I'll give you as much time as</p> <p>7 you want after I direct you to certain portions of the</p> <p>8 document, and then you can take a look at it. Okay?</p> <p>9 <b>A. Okay.</b></p> <p>10 Q. Is that fair?</p> <p>11 <b>A. Potentially.</b></p> <p>12 Q. Okay.</p> <p>13 <b>A. It's a 23-page document.</b></p> <p>14 Q. I understand. Some of it has topics in here</p> <p>15 that don't really concern us and others do not, but</p> <p>16 you're welcome to review the whole document. If you</p> <p>17 look at the first page, or, you know, go towards the</p> <p>18 last page, whatever makes sense to you, it's a document</p> <p>19 that is coming from the Food &amp; Drug Administration or</p> <p>20 FDA, correct?</p> <p>21 <b>A. Correct.</b></p> <p>22 Q. To Boston Scientific, correct?</p> <p>23 MS. GAYLE: Objection. Form. He's already asked</p> <p>24 to review the whole document.</p> <p>25</p>	<p style="text-align: right;">Page 735</p> <p>1 representation. But this is from FDA to Boston</p> <p>2 Scientific. And the FDA states, at No. 8, The Material</p> <p>3 Safety Data Sheet provided for the Marlex material</p> <p>4 states that the product used is for coatings. In this</p> <p>5 MSDS, there is a medical application caution that states</p> <p>6 do not use this Chevron Phillips Chemical Company</p> <p>7 material in medical applications involving permanent</p> <p>8 implantation in the human body or permanent contact with</p> <p>9 internal body fluids or tissues. Did I read that</p> <p>10 correctly?</p> <p>11 <b>A. I see it.</b></p> <p>12 Q. That's the same language we just looked at</p> <p>13 together, correct, for the Marlex polypropylene</p> <p>14 material?</p> <p>15 <b>A. It appears to be similar.</b></p> <p>16 Q. It's actually identical, but you can compare</p> <p>17 the language in both. And the FDA says to Boston</p> <p>18 Scientific, Please provide a rationale why your mesh</p> <p>19 material is safe for use as a permanent implant device</p> <p>20 contrary to what is stated in the MSDS provided for the</p> <p>21 Marlex material. Do you see that?</p> <p>22 MS. GAYLE: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. I see that.</b></p> <p>25 Q. So the FDA is asking Boston Scientific, Hey,</p>
<p style="text-align: right;">Page 734</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Well, I'm just looking at the address. It's</p> <p>3 addressed to Boston Scientific?</p> <p>4 MS. GAYLE: It's a compilation of multiple</p> <p>5 documents.</p> <p>6 BY THE WITNESS:</p> <p>7 <b>A. Yeah. I don't feel -- I mean, this is a</b></p> <p>8 <b>complicated -- it's a very important, complicated</b></p> <p>9 <b>document that is just now presented to me after we could</b></p> <p>10 <b>have reviewed this yesterday, and so -- and this is not</b></p> <p>11 <b>just one, and there's letters back and forth.</b></p> <p>12 Q. Doctor, I want to give you as much time as you</p> <p>13 need to review it, but let me point you to certain</p> <p>14 sections. And then, if you need more time, feel free.</p> <p>15 If you go to -- do you see at the bottom there is what</p> <p>16 we call Bates numbers?</p> <p>17 <b>A. Yes, I see those.</b></p> <p>18 Q. Do you see they begin with DX?</p> <p>19 <b>A. Yes.</b></p> <p>20 Q. If you go to the page that has DX0046-005?</p> <p>21 <b>A. Yes, I see. I'm there.</b></p> <p>22 Q. Okay. Do you see at No. 8, paragraph 8?</p> <p>23 <b>A. Yes.</b></p> <p>24 Q. And this is from FDA. And you can look at the</p> <p>25 document to make yourself comfortable with my</p>	<p style="text-align: right;">Page 736</p> <p>1 we see this medical application caution language. We</p> <p>2 want to understand why you think the mesh is safe to use</p> <p>3 in the human body. Is that a fair summary?</p> <p>4 MS. GAYLE: Object to form.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A. I see what they're stating in this one number</b></p> <p>7 <b>here, yes.</b></p> <p>8 Q. And then, if you flip with me a couple more</p> <p>9 pages to the document at the bottom that has 009 --</p> <p>10 <b>A. Okay.</b></p> <p>11 Q. -- and do you see, at the top, it says,</p> <p>12 Response to FDA questions?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. And it has FDA Question No. 8 below there, do</p> <p>15 you see that?</p> <p>16 <b>A. I see it.</b></p> <p>17 Q. And that's the same question that FDA had that</p> <p>18 we just read previously, correct?</p> <p>19 <b>A. I see it.</b></p> <p>20 Q. And, at the bottom, underneath that, it says,</p> <p>21 BSC response, or Boston Scientific company response?</p> <p>22 <b>A. I see it.</b></p> <p>23 Q. And with respect to the Marlex polypropylene</p> <p>24 MSDS sheet, at the second paragraph, Boston Scientific</p> <p>25 states that, in 2002, Boston Scientific was informed</p>

<p style="text-align: right;">Page 737</p> <p>1 that Phillips Sumika no longer would supply this resin</p> <p>2 for any application involving implantation in the human</p> <p>3 body due to the company's unwillingness to accept any</p> <p>4 liability for the use of their resin for medical</p> <p>5 purposes, particularly permanent implants. They</p> <p>6 subsequently revised the MSDS for Marlex to this effect.</p> <p>7 Do you see that?</p> <p>8 <b>A. Yes.</b></p> <p>9 MS. GAYLE: Object to form.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. So do you see there Boston Scientific is</p> <p>12 reporting to FDA that Phillips Sumika told them they</p> <p>13 would not supply the polypropylene resin due to their</p> <p>14 own concern for liability? And then underneath that, it</p> <p>15 says, However, in 2004, Boston Scientific entered into a</p> <p>16 one-year contract with Phillips Sumika to enable Boston</p> <p>17 Scientific Corporation to purchase the resin with the</p> <p>18 understanding that Boston Scientific would use this</p> <p>19 material in the manufacture of medical devices which may</p> <p>20 be implanted in the human body. The agreement required</p> <p>21 Boston Scientific to be ultimately responsible for</p> <p>22 ensuring that the material was suited to the specific</p> <p>23 application and assume all product liability. Do you</p> <p>24 see that?</p> <p>25 <b>A. Yeah.</b></p>	<p style="text-align: right;">Page 739</p> <p>1 polypropylene manufacturer from product liability?</p> <p>2 Knowing that, should they have communicated that to</p> <p>3 doctors?</p> <p>4 MS. GAYLE: Object to form. Object to the</p> <p>5 characterization of the Phillip Sumika's intent or</p> <p>6 reasoning for putting that in there, and object to</p> <p>7 counsel testifying on behalf of the company, and object</p> <p>8 to the use of this document. We weren't provided this</p> <p>9 previously. I don't even believe it's on his reliance</p> <p>10 list, Counsel.</p> <p>11 MS. GEIST: Well, I understand that you all --</p> <p>12 MS. GAYLE: He's asked for the opportunity to</p> <p>13 review it.</p> <p>14 MS. GEIST: -- didn't give your own expert this</p> <p>15 information. That would have been helpful for a doctor</p> <p>16 to know the full story.</p> <p>17 MS. GAYLE: That's an unfair characterization,</p> <p>18 Counsel. In addition, he's asked to review the document</p> <p>19 that you're trying to ask him questions for, and then</p> <p>20 you're saying that the company -- you're testifying for</p> <p>21 the company. They're trying to keep this out. It's</p> <p>22 ridiculous. So my objection stands.</p> <p>23 BY THE WITNESS:</p> <p>24 <b>A. I have yet to see a document which has Bard's</b></p> <p>25 <b>name on it saying it's okay to use in the implantation</b></p>
<p style="text-align: right;">Page 738</p> <p>1 Q. And then, ultimately, as I think you already</p> <p>2 know, Doctor, from your own experience, FDA cleared,</p> <p>3 through the 510 clearance process, the Pinnacle device,</p> <p>4 which is the subject of this correspondence between FDA</p> <p>5 and Boston Scientific?</p> <p>6 MS. GAYLE: Object to form.</p> <p>7 BY MS. GEIST:</p> <p>8 Q. Are you aware of that?</p> <p>9 <b>A. I have no data to support that. I have not</b></p> <p>10 <b>seen those documents.</b></p> <p>11 Q. Well, it's part of this overall package, the</p> <p>12 FDA's approval of the Pinnacle product. It's part of</p> <p>13 this, Doctor. And I'm happy to have you read it cover</p> <p>14 to cover.</p> <p>15 MS. GAYLE: And he's asked to review the document.</p> <p>16 And so my objection continues with asking him questions</p> <p>17 when he's not even reviewed the document.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. And, Doctor, I guess my question to you is</p> <p>20 this, after being informed of the reasons why the</p> <p>21 Phillips Sumika Company added that medical application</p> <p>22 caution language to the MSDS sheet, does that change</p> <p>23 your opinion at all that Bard should have included that</p> <p>24 information in the IFU for the Avaulta products knowing</p> <p>25 that the only reason it was included was to insulate the</p>	<p style="text-align: right;">Page 740</p> <p>1 <b>of humans. I see Boston Scientific everywhere.</b></p> <p>2 Q. Now, that is the same Marlex polypropylene</p> <p>3 that we just looked at which is set forth in the MSDS</p> <p>4 sheet for the Avaulta products, true?</p> <p>5 MS. GAYLE: Object to form.</p> <p>6 BY MS. GEIST:</p> <p>7 Q. If you compare -- if you look at the document</p> <p>8 I just gave you, Doctor, and the MSDS sheet, it is the</p> <p>9 same Marlex polypropylene? It is the very same, from</p> <p>10 the very same company? Do you see that?</p> <p>11 <b>A. I see that.</b></p> <p>12 Q. So does it matter whether or not there is</p> <p>13 Bard's name on it, that Boston Scientific is telling FDA</p> <p>14 exactly why Phillips Sumika added that language to the</p> <p>15 MSDS sheet?</p> <p>16 MS. GAYLE: Object to form.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A. I don't know of all of the manufacturing</b></p> <p>19 <b>processes that go on after the product is delivered to</b></p> <p>20 <b>Boston Scientific versus Bard. All I see here is Boston</b></p> <p>21 <b>Scientific. Boston Scientific gained permission. I</b></p> <p>22 <b>don't see Bard ever gaining permission, and they're</b></p> <p>23 <b>actually trying to hide that fact.</b></p> <p>24 Q. Does this document at all relieve your concern</p> <p>25 that there was any scientific or medical reason for the</p>



<p style="text-align: right;">Page 741</p> <p>1 inclusion of the medical application caution language in  2 the MSDS sheet to begin with?  3 MS. GAYLE: Object to form.  4 BY MS. GEIST:  5 Q. I mean, you haven't seen a single document, an  6 article or a study, that caused the Phillips Sumika  7 company to put that language in the MSDS sheet, have  8 you?  9 MS. GAYLE: Object to form.  10 BY THE WITNESS:  11 <b>A. I've seen the opposite. I've seen the</b>  12 <b>representative of that company saying it should be taken</b>  13 <b>seriously.</b>  14 Q. So you're sticking with that opinion  15 regardless of what I just showed you; is that correct?  16 MS. GAYLE: Objection. Mischaracterizes his  17 testimony. And moved to strike counsel's preface before  18 the question.  19 BY MS. GEIST:  20 Q. Do you want to at least review the materials  21 I've provided to you, Dr. Elliott, and see if that has  22 any impact on the opinions you've given in this  23 litigation to a reasonable degree of medical certainty?  24 <b>A. Yeah. It's 23 pages. For me to read that</b>  25 <b>will take at least two to three minutes per page, and I</b></p>	<p style="text-align: right;">Page 743</p> <p>1 <b>A. No. That was at the Palmer Hotel where I'm</b>  2 <b>staying. And then last night I met with Ms. Gayle for,</b>  3 <b>roughly, 15, 20 minutes at the Palmer Hotel, again,</b>  4 <b>going over just discussion for today, and that's it.</b>  5 Q. Any other meetings with any other plaintiffs  6 to prepare for your deposition today?  7 <b>A. No.</b>  8 Q. Or yesterday?  9 <b>A. No. Just those two telephone calls that I can</b>  10 <b>recall. I believe that was all there was for, again,</b>  11 <b>roughly, whatever times I told you.</b>  12 Q. And, in terms of the total number of hours  13 you've spent reviewing information and preparing for  14 your deposition, that would be reflected in your  15 invoices to counsel, I assume?  16 <b>A. That's correct. That would be -- that would</b>  17 <b>be the accurate representation of the time that I spent</b>  18 <b>in totality on this project.</b>  19 Q. And would that provide a narrative that would  20 be helpful to somebody like me that actually say things  21 like preparation for deposition or similar language?  22 <b>A. Yes. It would have prepare -- preparation for</b>  23 <b>deposition and then review of pertinent manuscripts</b>  24 <b>could be the same thing. So it's not going to be just</b>  25 <b>specific just "deposition."</b></p>
<p style="text-align: right;">Page 742</p> <p>1 <b>may -- I may have to correlate that. So that will be,</b>  2 <b>roughly, 45 minutes or longer, and I will do that.</b>  3 Q. I'm just saying. You don't have to do it now.  4 But my question to you is, would you want to review the  5 information I provided to you to see if it changes your  6 opinions at all?  7 <b>A. Absolutely.</b>  8 Q. Doctor, before your deposition today in the  9 three cases -- Mrs. Alonso's case, Mrs. Wheeler's case,  10 and Mrs. Bolyard's case -- can you just tell me briefly  11 what you did to prepare for your testimony?  12 <b>A. I reviewed medical literature, combining that</b>  13 <b>with my 20-some odd years of medical experience. I</b>  14 <b>reviewed depositions. I had an hour-and-12-minute</b>  15 <b>conversation with Mr. Cartmell in one day. I had an</b>  16 <b>hour-and-21-minute conversation the other day. I</b>  17 <b>reviewed my expert report, those things.</b>  18 Q. Those two conversations with Mr. Cartmel that  19 you just described to me, did you have any other  20 conversations or meetings with plaintiff's counsel to  21 prepare for your testimony today or yesterday?  22 <b>A. On Saturday morning, I met with Mr. Cartmel</b>  23 <b>for, roughly, 15 minutes.</b>  24 Q. And was that here at the Wexler Wallace's  25 offices, Wexler Wallace office in Chicago?</p>	<p style="text-align: right;">Page 744</p> <p>1 Q. Got it. And we've already asked for that  2 information, which has not yet been provided to us.  3 You're aware of that, correct?  4 <b>A. I'm not aware of that, no. I know you've</b>  5 <b>requested it. I've heard that, but I don't know what</b>  6 <b>you've received.</b>  7 Q. Okay. Sitting here today, I assume you can't  8 give me your best approximation or estimate of how much  9 time you actually spent preparing to give testimony  10 today and yesterday?  11 MS. GAYLE: Objection. Form.  12 BY THE WITNESS:  13 <b>A. Well, in reality, preparation for today began</b>  14 <b>20-something years ago. So you can't exclude that</b>  15 <b>experience, but then it also began in June or July,</b>  16 <b>whenever I began on this project, too.</b>  17 Q. Well, but you're not going to bill for time 20  18 years ago, though, right, Doctor?  19 <b>A. No. I'm not going to bill.</b>  20 Q. That would be a pretty big bill?  21 <b>A. So billing began in June, but preparation</b>  22 <b>began during fellowship, residency, medical school even.</b>  23 <b>So I know what you're saying, and I'm not trying -- but</b>  24 <b>I'm trying to also say this is not just preparation for</b>  25 <b>this. There has been a vast amount of preparation.</b></p>



<p style="text-align: right;">Page 745</p> <p>1 Q. No. I understand that. I just didn't know if</p> <p>2 you could tell me there was a specific day, for example,</p> <p>3 where you said to yourself, Okay, I need to start</p> <p>4 preparing for my deposition. Let me hunker down and go</p> <p>5 through my reports and look at literature and things of</p> <p>6 that nature?</p> <p>7 A. In reality, that probably would be -- sorry.</p> <p>8 In reality, that began probably the first day I reviewed</p> <p>9 medical records. Because having going through this</p> <p>10 process before, when I start looking at those things,</p> <p>11 that is preparation.</p> <p>12 I am -- the only time I'm preparing</p> <p>13 specifically for my own deposition is probably when I'm</p> <p>14 reviewing another person's deposition. But that's also</p> <p>15 not necessarily true because I'm correlating that to</p> <p>16 medical records, so it gets complicated.</p> <p>17 Q. And, in terms of prior testimony, do you</p> <p>18 remember yesterday we talked a little bit about whether</p> <p>19 or not you were a biomaterials expert. And you said to</p> <p>20 me, I would want to see that testimony, and I didn't</p> <p>21 have it for you?</p> <p>22 A. Yes.</p> <p>23 Q. Do you still want to see it?</p> <p>24 A. If we want to continue that line of</p> <p>25 questioning.</p>	<p style="text-align: right;">Page 747</p> <p>1 A. Well, again, it depends upon what we're</p> <p>2 talking about as far as biomaterials expert. I do have</p> <p>3 expertise, the papers I've written, both in animals and</p> <p>4 in humans, studying them under the microscope, as we've</p> <p>5 already mentioned today, so the mesh complications,</p> <p>6 other medical devices and which are all biomaterials.</p> <p>7 So I do have a certain expertise in that</p> <p>8 subject. Do I hold an advanced degree of Ph.D. in</p> <p>9 biomaterials? The answer to that is, no. So, again,</p> <p>10 it's not that the testimony is inconsistent. I'm</p> <p>11 putting -- I'm describing it better.</p> <p>12 Q. Okay. And that is a better description. So</p> <p>13 your testimony is from a clinician's perspective rather</p> <p>14 than an advanced degree, biomaterials scientist; is that</p> <p>15 a fair summary?</p> <p>16 A. I would agree with you with that,</p> <p>17 yes.</p> <p>18 MS. GEIST: Okay. Dr. Elliott, I want to thank</p> <p>19 you very much for your time and your patience. And I</p> <p>20 don't have any further questions for you at this</p> <p>21 time.</p> <p>22 THE WITNESS: Okay.</p> <p>23 CROSS-EXAMINATION</p> <p>24 BY MS. GAYLE:</p> <p>25 Q. Good afternoon, Dr. Elliott. I have some</p>
<p style="text-align: right;">Page 746</p> <p>1 Q. Well, I just want to know from you. I had</p> <p>2 asked you yesterday if you were holding yourself out as</p> <p>3 a biomaterials expert. And I had stated to you, with</p> <p>4 all intention -- intentions of being accurate, that I</p> <p>5 had read your prior testimony where you appeared as an</p> <p>6 expert in the Ethicon Pelvic Mesh Litigation where you</p> <p>7 had said, I'm not a biomaterials expert and you didn't</p> <p>8 hold yourself out as a polymer chemist and things of</p> <p>9 that nature. So I just want to make sure you're giving</p> <p>10 the same testimony in this litigation as you did in that</p> <p>11 litigation?</p> <p>12 MS. GAYLE: Object to form. His testimony from</p> <p>13 yesterday is what it is.</p> <p>14 BY THE WITNESS:</p> <p>15 A. I put qualifiers on what I stated yesterday.</p> <p>16 I do not recall the Ethicon testimony word for word. I</p> <p>17 don't know if Mr. Snell had put qualifiers on his</p> <p>18 question. But I answered that, and I'll stand by my</p> <p>19 answer as far as what the various different qualifiers I</p> <p>20 put on there.</p> <p>21 Q. If you said, yeah, I'm not a biomaterials</p> <p>22 expert, you have no reason to change that testimony and</p> <p>23 say something different in this litigation, true?</p> <p>24 MS. GAYLE: Object to form.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 748</p> <p>1 follow-up questions. I'll try to make it as fast as we</p> <p>2 can.</p> <p>3 A. Okay.</p> <p>4 Q. I know that we all have flights this evening.</p> <p>5 If you'll turn back to meet with me to Exhibit 39 --</p> <p>6 A. Okay.</p> <p>7 Q. -- Bates number ending, I believe, with</p> <p>8 DX0046-009?</p> <p>9 A. Yes.</p> <p>10 Q. 009 is the last three digits on the page,</p> <p>11 Doctor?</p> <p>12 A. Okay. I'm there.</p> <p>13 Q. And, Doctor, do you remember your line of</p> <p>14 questioning where counsel asked you various questions</p> <p>15 over this packet of documents? Do you remember that</p> <p>16 just moments ago?</p> <p>17 A. I remember well.</p> <p>18 Q. Okay. And I'm going to refer you to -- to a</p> <p>19 statement. She referred you to BSC's response on this</p> <p>20 particular page. Under the heading, Background, Doctor,</p> <p>21 if you go three paragraphs down, okay?</p> <p>22 A. Okay. I'm there.</p> <p>23 Q. The paragraph starting in, However?</p> <p>24 A. Yes.</p> <p>25 Q. The last sentence of that paragraph, will you</p>

<p style="text-align: right;">Page 749</p> <p>1 read that last sentence into the record, please?</p> <p>2 <b>A. The agreement required Boston Scientific to be</b></p> <p>3 <b>ultimately responsible for ensuring that the material is</b></p> <p>4 <b>suited to the specific application and assume all</b></p> <p>5 <b>product liability.</b></p> <p>6 Q. Doctor, with regard to Bard and the use of</p> <p>7 Marlex in its Avaulta Plus and Avaulta Solo products,</p> <p>8 have you ever seen where Bard has assumed responsibility</p> <p>9 for any product liability?</p> <p>10 MS. GEIST: Objection to form.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A. In the documents I've reviewed, I have not</b></p> <p>13 <b>read that, no.</b></p> <p>14 Q. In fact, Doctor, in the documents that you've</p> <p>15 reviewed, I believe that you testified that you actually</p> <p>16 had seen where Bard tried to hide the use of this</p> <p>17 Marlex; is that correct?</p> <p>18 MS. GEIST: Objection to form.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A. I reviewed a series of e-mails where there was</b></p> <p>21 <b>active attempts to hide how Bard was using the product,</b></p> <p>22 <b>yes.</b></p> <p>23 Q. And let me just fix my question, Doctor, so I</p> <p>24 don't have any objections. Did Bard try to hide the use</p> <p>25 of Marlex in its Avaulta Plus product?</p>	<p style="text-align: right;">Page 751</p> <p>1 <b>A. I reserve the right to supplement this report</b></p> <p>2 <b>if new or supplemental information is provided at any</b></p> <p>3 <b>point and as I review other related documents.</b></p> <p>4 Q. And, Doctor, I believe that you were asked a</p> <p>5 series of questions about whether or not you had</p> <p>6 reviewed the transcripts of treating physicians at the</p> <p>7 time that you had executed your report. Do you remember</p> <p>8 that line of questioning?</p> <p>9 <b>A. I vaguely remember that, yes.</b></p> <p>10 Q. And should available information or</p> <p>11 transcripts become available to you, would you be</p> <p>12 willing to review those, Doctor?</p> <p>13 <b>A. I would want --</b></p> <p>14 MS. GEIST: Objection. Form. You can answer,</p> <p>15 Doctor.</p> <p>16 BY THE WITNESS:</p> <p>17 <b>A. Okay. No. I would want to review -- if</b></p> <p>18 <b>documents become available, whether they be medical</b></p> <p>19 <b>transcripts, depositions, any new information that shed</b></p> <p>20 <b>light on this subject, I would be very willing to read</b></p> <p>21 <b>those.</b></p> <p>22 Q. And if your opinions change, Doctor, then</p> <p>23 would you issue an amended report?</p> <p>24 <b>A. Well, I keep an open mind. And if an amended</b></p> <p>25 <b>report is required or needed or helpful, then we would</b></p>
<p style="text-align: right;">Page 750</p> <p>1 MS. GEIST: Objection to form, inferring Bard's</p> <p>2 intent from company documents.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A. The e-mails that I reviewed stated, and we can</b></p> <p>5 <b>pull those out and state them if you'd like, but,</b></p> <p>6 <b>ultimately, multiple times do not let the company -- do</b></p> <p>7 <b>not let Phillips Sumika -- Sumika know that we are doing</b></p> <p>8 <b>this. Do not -- do not -- make sure they do not have</b></p> <p>9 <b>that information.</b></p> <p>10 Q. So they weren't forthcoming with that</p> <p>11 information, correct, Doctor?</p> <p>12 MS. GEIST: Objection to form, infers Bard's intent</p> <p>13 from company documents.</p> <p>14 BY THE WITNESS:</p> <p>15 <b>A. All I can go off is that series of e-mails</b></p> <p>16 <b>where it does not take an M.D. or a Ph.D. It is very</b></p> <p>17 <b>clear to anybody what their intent was.</b></p> <p>18 Q. Let's go down to Ms. Bolyard's report now,</p> <p>19 Doctor, Exhibit 35. And I'm just going to kind of go</p> <p>20 back, backwards, if you don't mind.</p> <p>21 <b>A. Okay.</b></p> <p>22 Q. Doctor, if you turn to the first page of</p> <p>23 Exhibit 35, the first paragraph, can you read into the</p> <p>24 record the first sentence -- the last sentence of that</p> <p>25 first paragraph, Doctor, starting with, I reserve?</p>	<p style="text-align: right;">Page 752</p> <p>1 <b>do that.</b></p> <p>2 Q. And do you know, at the time of your report,</p> <p>3 Doctor, whether or not the transcripts for those</p> <p>4 treaters were available to you?</p> <p>5 <b>A. I don't know that.</b></p> <p>6 MS. GEIST: Objection to form.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. And, Doctor, I think on Ms. Bolyard you were</p> <p>9 also asked a series of questions with regard to her</p> <p>10 sexual status. Do you remember that line of</p> <p>11 questioning?</p> <p>12 <b>A. In general, yes.</b></p> <p>13 Q. Do you remember the questions about her</p> <p>14 husband who suffered from erectile dysfunction?</p> <p>15 <b>A. Yes.</b></p> <p>16 Q. Doctor, in your experience and practice, is it</p> <p>17 possible that a woman be engaging in physical intimacy</p> <p>18 with her husband if he has erectile dysfunction?</p> <p>19 MS. GEIST: Objection to form.</p> <p>20 BY THE WITNESS:</p> <p>21 <b>A. Oh, it's possible, yes.</b></p> <p>22 Q. And, in fact, that condition would not keep --</p> <p>23 prohibit him completely from having intimate -- intimacy</p> <p>24 with his wife, would it?</p> <p>25 MS. GEIST: Objection to form.</p>

In Re: CR Bard 200

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<p style="text-align: right;">Page 753</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A. By no means. I'm a urologist. As compared to</b></p> <p>3 <b>a gynecologist who only sees women, I also see men.</b></p> <p>4 <b>25 -- 25 percent of my practice is male. So we are</b></p> <p>5 <b>treating impotence. Impotence in and of itself does not</b></p> <p>6 <b>inhibit sexual activity. It may make it a little more</b></p> <p>7 <b>difficult, but there are treatments available.</b></p> <p>8 Q. And, likewise, Doctor, if, for some reason, as</p> <p>9 counsel had inferred that his erectile dysfunction was</p> <p>10 completely inhibiting him from having sex, then that</p> <p>11 doesn't mean that the couple could not be having sex</p> <p>12 through other methods, including, perhaps, the use of a</p> <p>13 dildo, correct?</p> <p>14 MS. GEIST: Objection to form.</p> <p>15 BY THE WITNESS:</p> <p>16 <b>A. As a urologist dealing with pelvic floor,</b></p> <p>17 <b>there are a lot of different ways to have intercourse.</b></p> <p>18 MS. GEIST: I'm going to object to this whole line</p> <p>19 of questioning.</p> <p>20 MS. GAYLE: You brought it up, Counsel. You</p> <p>21 inferred they weren't having sex. And so I apologize I</p> <p>22 have to go through for everybody in the room.</p> <p>23 MS. GEIST: I did not say anything about a dildo.</p> <p>24 Lord knows I did not.</p> <p>25</p>	<p style="text-align: right;">Page 755</p> <p>1 <b>a lot of questions over two days, so I don't remember.</b></p> <p>2 <b>I mean, I remember in generality.</b></p> <p>3 Q. Sure. So let's just break it down for you,</p> <p>4 Doctor. When you spoke with Ms. Wheeler, did you</p> <p>5 measure her dyspareunia on the VAS scale?</p> <p>6 MS. GEIST: Objection to form.</p> <p>7 BY THE WITNESS:</p> <p>8 <b>A. Yes. I used the Visual Analog Pain Scale and</b></p> <p>9 <b>current situation. If sexual activity were to take</b></p> <p>10 <b>place -- she graded it, not I -- she graded it as an 8.</b></p> <p>11 Q. And, Doctor, have you found that that VAS</p> <p>12 scale is a reliable instrument of measure?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Measurement?</p> <p>15 MS. GEIST: Objection to form.</p> <p>16 BY THE WITNESS:</p> <p>17 <b>A. There have been multiple studies that the</b></p> <p>18 <b>Visual Analog Scale is highly reproducible for an</b></p> <p>19 <b>individual.</b></p> <p>20 Q. And, Doctor, I believe, if you also turn to</p> <p>21 the first page -- just one moment. Let me make sure I'm</p> <p>22 on Wheeler. Doctor, turn to page 3 of Ms. Wheeler's</p> <p>23 report, if you would.</p> <p>24 <b>A. I'm there.</b></p> <p>25 Q. And I believe there was discussion going back</p>
<p style="text-align: right;">Page 754</p> <p>1 BY MS. GAYLE:</p> <p>2 Q. Doctor, there's other ways that couples can</p> <p>3 engage in sexual relations; isn't that correct, other</p> <p>4 than penetration?</p> <p>5 <b>A. There is a lot of different ways that sexual</b></p> <p>6 <b>activity can take place.</b></p> <p>7 Q. Thank you, Doctor. And, Doctor, with regard</p> <p>8 to all three of the questions and in the interest of</p> <p>9 time, you performed differential -- differential</p> <p>10 diagnosis for all three ladies as we've -- as you've</p> <p>11 discussed today, correct?</p> <p>12 <b>A. Correct.</b></p> <p>13 MS. GEIST: Objection. Asked and answered.</p> <p>14 BY MS. GAYLE:</p> <p>15 Q. And, Doctor, I'm going to skip over to</p> <p>16 Ms. Wheeler now. You can grab hers, and I don't exactly</p> <p>17 have which number that was.</p> <p>18 <b>A. I have Wheeler's, No. 33.</b></p> <p>19 Q. Yes. Thank you. You were asked a series of</p> <p>20 questions about her degree of dyspareunia. I believe</p> <p>21 counsel quoted to you that it was a lesser degree of</p> <p>22 dyspareunia in the records than the more severe degree</p> <p>23 that Ms. Wheeler discussed with you. Do you remember</p> <p>24 that line of questioning earlier today?</p> <p>25 <b>A. Actually, I do not remember it. There's been</b></p>	<p style="text-align: right;">Page 756</p> <p>1 and forth, and it could have been Ms. Alonso. But just</p> <p>2 for the record to clarify, first paragraph, Ms. Wheeler</p> <p>3 had the Solo posterior and Solo anterior, correct?</p> <p>4 <b>A. Correct.</b></p> <p>5 Q. And Ms. Alonso, can you turn to hers? And it</p> <p>6 might be around exhibit -- do you have it?</p> <p>7 <b>A. Yes, I do.</b></p> <p>8 Q. And, similarly, can you tell me what product</p> <p>9 she had, Doctor?</p> <p>10 <b>A. According to my records, she had an Avaulta</b></p> <p>11 <b>anterior and the Align transobturator sling.</b></p> <p>12 Q. And, Doctor, if it were the product that had</p> <p>13 the Avaulta Plus, then I think you testified earlier or</p> <p>14 at some point today that a patient would be at a higher</p> <p>15 risk than if it would have been the Avaulta Solo,</p> <p>16 correct?</p> <p>17 MS. GEIST: Objection to form. Higher risk of</p> <p>18 what?</p> <p>19 MS. GAYLE: Higher risk of complications.</p> <p>20 MS. GEIST: Objection to form.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A. There is data available demonstrating, from</b></p> <p>23 <b>internal documents, external reviews, manuscripts, that,</b></p> <p>24 <b>when the collagen is implanted, then there's increased</b></p> <p>25 <b>hypersensitivity and decreased healing with the Avaulta</b></p>

<p style="text-align: right;">Page 757</p> <p>1 <b>Plus.</b></p> <p>2 Q. And, Doctor, with regard to each of the three</p> <p>3 ladies, you were asked a series of questions about the</p> <p>4 implantation methods. So I'm going to break it down.</p> <p>5 With regard to Ms. Alonso, did you see</p> <p>6 anything that was outside the standard of care in her</p> <p>7 implantation of mesh?</p> <p>8 MS. GEIST: Objection to form.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A. No.</b></p> <p>11 Q. And the same question for Ms. Wheeler.</p> <p>12 Doctor, did you see anything outside the standard of</p> <p>13 care for the implantation of her Avaulta devices or</p> <p>14 Align device?</p> <p>15 <b>A. In review of the --</b></p> <p>16 MS. GEIST: Objection to form. Asked and answered.</p> <p>17 You can go ahead, Doctor.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A. In the review of the operative note, I did not</b></p> <p>20 <b>see anything that stated it was outside the standard of</b></p> <p>21 <b>care.</b></p> <p>22 Q. And the same question for Ms. Bolyard?</p> <p>23 <b>A. Same answer, review of the surgical operative</b></p> <p>24 <b>note, I saw nothing outside the standard of care.</b></p> <p>25 Q. And, Doctor, again, let's go back to each one</p>	<p style="text-align: right;">Page 759</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A. No.</b></p> <p>3 Q. That includes smoking on behalf of Ms. Bolyard</p> <p>4 as well, Doctor?</p> <p>5 MS. GEIST: Same objection.</p> <p>6 BY THE WITNESS:</p> <p>7 <b>A. Yeah. We went over that earlier. I saw</b></p> <p>8 <b>nothing in there that her history of smoking led to her</b></p> <p>9 <b>product complication.</b></p> <p>10 Q. And, Doctor, I think that you, early in</p> <p>11 this day, were asked a series of questions and</p> <p>12 counsel had inferred that you had gotten rid of your</p> <p>13 notes.</p> <p>14 Is your process, as I understood it, is your</p> <p>15 process an evolution where you go from a notepad to a</p> <p>16 Word document and that Word document evolves into your</p> <p>17 eventual final product?</p> <p>18 MS. GEIST: Objection to form. Asked and answered.</p> <p>19 We went over this a long time. And objection to any</p> <p>20 statement about what I was inferring.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A. Correct. I agree with you.</b></p> <p>23 MS. GAYLE: Okay. Okay. All right. We're done.</p> <p>24 Thank you, Doctor.</p> <p>25 MS. GEIST: Thank you, Doctor.</p>
<p style="text-align: right;">Page 758</p> <p>1 of these three questions or three cases with regard to</p> <p>2 particular activities of the lady.</p> <p>3 With regard to Ms. Alonso, did you say that</p> <p>4 she engaged in sexual activity in a way that would have</p> <p>5 caused her complications? In other words, prematurely</p> <p>6 engaged in sexual activity?</p> <p>7 MS. GEIST: Objection to form.</p> <p>8 BY THE WITNESS:</p> <p>9 <b>A. I saw nothing in the records that she</b></p> <p>10 <b>was engaged in sexual activity too early or anything</b></p> <p>11 <b>that would predispose her to failure or</b></p> <p>12 <b>complications.</b></p> <p>13 Q. And did you see anything in the records or</p> <p>14 learn anything regarding Ms. Wheeler that would</p> <p>15 indicate that she engaged in sexual activities</p> <p>16 prematurely?</p> <p>17 <b>A. Same answer. I saw nothing in the records to</b></p> <p>18 <b>support that.</b></p> <p>19 Q. And same questions for Ms. Bolyard?</p> <p>20 <b>A. And same answer. I saw nothing in the</b></p> <p>21 <b>records.</b></p> <p>22 Q. Did you see anything in the records that would</p> <p>23 predispose any of these women to have caused their own</p> <p>24 complications from these products?</p> <p>25 MS. GEIST: Objection to form. Asked and answered.</p>	<p style="text-align: right;">Page 760</p> <p>1 VIDEO TECHNICIAN: This concludes today's</p> <p>2 deposition of Dr. Daniel Elliot. We're off the record.</p> <p>3 The time is 3:41 p.m.</p> <p>4 (Witness excused.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

In Re: CR Bard 200

Daniel Elliott M.D., Vol. II

11/16/2014

<p style="text-align: right;">Page 761</p> <p>1 UNITED STATES OF AMERICA ) NORTHERN DISTRICT OF ILLINOIS ) 2 EASTERN DIVISION ) SS. STATE OF ILLINOIS ) 3 COUNTY OF COOK ) 4 5 I, Jennifer L. Bernier, Certified Shorthand 6 Reporter, Registered Professional Reporter, and Notary 7 Public, do hereby certify that DANIEL S. ELLIOT, M.D., 8 was first duly sworn by me to testify to the whole truth 9 and that the above deposition was reported 10 stenographically by me and reduced to typewriting under 11 my personal direction. 12 I further certify that the said deposition was 13 taken at the time and place specified and that the 14 taking of said deposition commenced on November 15 and 15 16th, 2014. 16 I further certify that I am not a relative or 17 employee or attorney or counsel of any of the parties, 18 nor a relative or employee of such attorney or counsel, 19 nor financially interested directly or indirectly in 20 this action. 21 22 23 24 25</p> <p style="text-align: right;">Page 762</p> <p>1 In witness whereof, I have hereunto set my 2 hand and affixed my seal of office at Chicago, Illinois, 3 this 5th day of November, A.D., 2014. 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <div style="text-align: center;">   <hr style="width: 20%; margin: 0 auto;"/>  JENNIFER L. BERNIER, CSR, RPR, CLR  CSR No. 084-004190 </div>	<p style="text-align: right;">Page 763</p> <p>1 TO: Daniel Elliott M.D., Vol. II 2 Re: Reading and Signing Your Deposition Transcript 3 Date Errata due back at our offices: 12/20/2014 4 5 Greetings: 6 You have reserved the right to read and sign your 7 deposition transcript. Please review the attached 8 PDF transcript, noting any changes or corrections 9 on the attached PDF Errata. You may fill out the 10 Errata electronically or print and fill out manually. 11 12 The PDF files open with Adobe Reader. If you need help 13 opening these files, please see the instructions in the 14 cover letter of this email. 15 16 Once you have completed your Errata, please print it, sign 17 it, and have the document notarized in the place provided. 18 19 When the signed Errata is returned to us, we will seal 20 and forward to the taking attorney to file with the 21 original transcript. We will also send copies of the 22 Errata to all ordering parties. 23 24 If the signed Errata is not returned within the time 25 below, the original transcript may be filed with the court without your signature. Please send completed Errata to: Tiffany Alley Global Reporting &amp; Video 730 Peachtree St. NE, Ste 470 Atlanta, GA 30308 (770) 343-9696</p> <p style="text-align: right;">Page 764</p> <p>1 ERRATA 2 I, the undersigned, do hereby certify that I have read the 3 transcript of my testimony, and that 4 ___ There are no changes noted. 5 ___ The following changes are noted: 6 7 Pursuant to Rule 30(7)(e) of the Federal Rules of Civil 8 Procedure and/or OCGA 9-11-30(e), any changes in form or 9 substance which you desire to make to your testimony shall 10 be entered upon the deposition with a statement of the 11 reasons given for making them. To assist you in making any 12 such corrections, please use the form below. If additional 13 pages are necessary, please furnish same and attach. 14 15 Page ____ Line ____ Change ____ 16 Reason for change ____ 17 Page ____ Line ____ Change ____ 18 Reason for change ____ 19 Page ____ Line ____ Change ____ 20 Reason for change ____ 21 Page ____ Line ____ Change ____ 22 Reason for change ____ 23 Page ____ Line ____ Change ____ 24 Reason for change ____ 25</p>
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<p style="text-align: right;">Page 765</p> <p>1 Page ____ Line ____ Change _____</p> <p>2 _____</p> <p>3 Reason for change _____</p> <p>4 Page ____ Line ____ Change _____</p> <p>5 _____</p> <p>6 Reason for change _____</p> <p>7 Page ____ Line ____ Change _____</p> <p>8 _____</p> <p>9 Reason for change _____</p> <p>10 Page ____ Line ____ Change _____</p> <p>11 _____</p> <p>12 Reason for change _____</p> <p>13 Page ____ Line ____ Change _____</p> <p>14 _____</p> <p>15 Reason for change _____</p> <p>16 Page ____ Line ____ Change _____</p> <p>17 _____</p> <p>18 Reason for change _____</p> <p>19 _____</p> <p>20 _____</p> <p style="text-align: center;">DEPONENT'S SIGNATURE</p> <p>21 _____</p> <p>Sworn to and subscribed before me this ____ day of</p> <p>22 _____, ____.</p> <p>23 _____</p> <p>24 NOTARY PUBLIC</p> <p>25 My Commission Expires: _____</p>	